

STATE OF VERMONT
Department of Banking, Insurance, Securities
And Health Care Administration

Division of Health Care Administration

Rule H-2009-03

Consumer Protection and Quality Requirements for Managed Care Organizations

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STATE OF VERMONT
DEPARTMENT OF BANKING, INSURANCE, SECURITIES
AND HEALTH CARE ADMINISTRATION

Division of Health Care Administration

Rule H-2009-03:
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PART 1: GENERAL PROVISIONS

- 1.1 Purpose. The purpose of this rule is to set forth the consumer protection and quality requirements that managed care organizations shall meet in order to further the purposes of its enabling statutes.
- 1.2 Authority. This rule is issued pursuant to the authority vested in the Commissioner of the Department of Banking, Insurance, Securities and Health Care Administration by 18 V.S.A. § 9414 and 8 V.S.A. §§ 15, 4089a, 4089b, and 4724.
- 1.3 Applicability, Scope and Delegation.
- (A) All managed care organizations and their delegates, including but not limited to health insurers, health maintenance organizations, preferred provider organizations, exclusive provider organizations, mental health review agents and all other financing mechanisms, systems and other entities that manage health care delivery for members or subscribers of any comprehensive major medical health benefit plan subject to the Department's jurisdiction shall operate in compliance with Parts 1 and 2 of this rule.
 - (B) In addition to Subsection (A) above, managed care organizations that use or administer utilization management mechanisms for members or subscribers of any comprehensive major medical health benefit plan subject to the Department's jurisdiction are also subject to Part 3 of this rule.
 - (C) In addition to Subsections (A) and (B) above, managed care organizations that use or administer pharmaceutical benefit management mechanisms for members or subscribers of any comprehensive major medical health benefit plan subject to the Department's jurisdiction are also subject to Part 4 of this rule.
 - (D) In addition to Subsections (A), (B) and (C) above, managed care organizations that contract with providers, use or administer networks, designate particular providers as preferred or otherwise use or administer any restrictions or incentives pertaining to use of certain providers by members or subscribers of any comprehensive major medical health benefit plan subject to the Department's jurisdiction are also subject to Part 5 of this rule.
 - (E) In addition to Subsections (A), (B) and (C) and (D) above, Part 6 of this rule shall apply to managed care organizations including, in relevant part, the mental health review agents

under contract with managed care organizations, when they issue and/or participate in administering comprehensive major medical health benefit plans and products subject to the Department's jurisdiction that:

1. Use utilization management mechanisms and financial incentives for members to use certain providers; and
2. Have 10,000 or more covered lives.

The Department in its sole discretion may choose to waive parts of the requirements in Part 6 for these managed care organizations and mental health review agents.

(F) Each managed care organization, including a mental health review agent and any delegate subject to this rule, in whole or in part, is accountable for ensuring that it operates in compliance with all applicable requirements of 18 V.S.A. § 9414 and 8 V.S.A. §§4089a, 4089b, and 4724, this rule, and any other applicable laws and rules, regardless of whether it is functioning as a delegate or the delegating entity. If a managed care organization delegates any activities or functions to other persons or entities, the managed care organization may not delegate its responsibility for the activities or functions, is accountable for ensuring that its delegates operate in compliance with all applicable requirements and shall maintain effective oversight of those activities, which shall include:

1. A written description of the delegate's activities and responsibilities, including reporting requirements;
2. Evidence of formal approval of the delegate's program by the managed care organization; and
3. A process by which the managed care organization at least annually evaluates the performance of the delegate and any sub-delegates, including but not limited to a process by which the managed care organization documents, tracks, addresses and resolves complaints from members and providers regarding the delegate's conduct and/or the conduct of any other managed care organization that performs any activities on its behalf.

1.4 Definitions.

- (A) "Adverse benefit determination" means a denial, reduction, modification or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit, including but not limited to:
1. a denial, reduction, termination or failure to provide or make payment that is based on a determination of a participant's or beneficiary's eligibility to participate in a health benefit plan;

2. a denial, reduction, modification or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit resulting from the application of any utilization review; and
 3. a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.
- (B) “Blueprint for Health” means the state's plan for chronic care infrastructure, prevention of chronic conditions, and chronic care management program, and includes an integrated approach to patient self-management, community development, health care system and professional practice change, and information technology initiatives.
- (C) “Case management” means a coordinated set of activities conducted to support the member and his/her health care provider in managing serious, complicated, protracted or other health conditions.
- (D) “Chronic care” means health services provided by a health care professional for an established clinical condition that is expected to last a year or more and that requires ongoing clinical management attempting to restore the individual to highest function, minimize the negative effects of the condition, and prevent complications related to chronic conditions. Examples of conditions that are or may be considered chronic include diabetes, hypertension, cardiovascular disease, cancer, asthma, pulmonary disease, substance abuse, mental illness, spinal cord injury, and hyperlipidemia.
- (E) “Chronic care management” means a system of coordinated health care interventions and communications for individuals with chronic conditions, including significant patient self-care efforts; systemic supports for the physician and patient relationship; and a plan of care emphasizing prevention of complications utilizing evidence-based practice guidelines, patient empowerment strategies, and evaluation of clinical, humanistic, and economic outcomes on an ongoing basis with the goal of improving overall health.
- (F) “Clinical peer” means a health care provider in a specialty that typically provides the procedure or treatment, or diagnoses or manages the medical condition under review and who holds a non-restricted license in a state of the United States.
- (G) “Clinical review criteria” means the written screening procedures, clinical protocols, practice guidelines and utilization management and review guidelines used by the managed care organization to determine the necessity and appropriateness of health care services.
- (H) “Commissioner” means the commissioner of the Vermont Department of Banking, Insurance, Securities and Health Care Administration or his or her designee.
- (I) “Concurrent review” means utilization review conducted during a member's stay in a hospital or other facility, or other ongoing course of treatment.

- (J) "Confidentiality code" means the confidentiality code adopted by the Department of Banking, Insurance, Securities and Health Care Administration on December 1, 1993 and any subsequent revisions.
- (K) "Contracted provider" means a provider employed by, under contract or subcontract with, in a network, designated as preferred or otherwise in an arrangement with a managed care organization for the purpose of furnishing health care services to the members of the managed care organization, regardless of the specific terms of or the terminology applied by the managed care organization to its relationship with the provider.
- (L) "Credentialing verification" or "credentialing reverification" means the process of obtaining and verifying information about a health care provider and evaluating that health care provider relative to the managed care organization's standards when that health care provider applies to become or remain a contracted provider with the managed care organization.
- (M) "Delegate" means an entity to which a managed care organization gives authority to carry out certain functions that the managed care organization would otherwise perform, or the act of giving authority to carry out certain functions to another entity.
- (N) "Department" means the Department of Banking, Insurance, Securities and Health Care Administration.
- (O) "Discharge plan" means the plan that results from the formal process for determining, before discharge from a health care facility, the coordination and management of the care that a member will receive following the discharge.
- (P) "Dose restriction" means imposing a restriction on the number of doses of prescription drug that will be covered during a specific time period. "Dose restriction" does not include a restriction on the number of doses when the prescription drug that is subject to the restriction cannot be supplied by or has been withdrawn from the market by the drug's manufacturer.
- (Q) "Emergency medical condition" means the sudden and, at the time, unexpected onset of an illness or medical condition that manifests itself by symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected by the prudent layperson, who possesses an average knowledge of health and medicine, to result in:
1. Placing the member's physical or mental health in serious jeopardy; or
 2. Serious impairment to bodily functions; or
 3. Serious dysfunction of any bodily organ or part.

- (R) "Emergency services" means health care items and services furnished or required to evaluate and treat an emergency medical condition.
- (S) "File", where used in the context of information to be provided to the Department by a managed care organization, means to file an original document by delivering it, and any copies as requested by the Department, to the Department of Banking, Insurance, Securities and Health Care Administration and, if requested by the Department, to an organization designated by the Department under Section 1.6(D). The Department may also, at its discretion, permit documents to be filed electronically.
- (T) "Generic drug" means a drug listed by generic name and considered to be chemically and therapeutically equivalent to a drug listed by brand name, as both names are identified in the most recent edition of the federal Food and Drug Administration's "Orange Book" of approved drug products.
- (U) "Grievance" means a complaint submitted by or on behalf of a member regarding the:
1. Adverse benefit determination;
 2. Availability, delivery or quality of health care services;
 3. Claims payment, handling or reimbursement for health care services; or
 4. Matters relating to the contractual relationship between a member and a managed care organization or the health insurer offering the health benefit plan.
- (V) "Gynecological health care services" means preventive and routine reproductive health and gynecological care, including annual screening, counseling, and treatment of gynecological disorders and diseases in accordance with the most current published recommendations of the American College of Obstetricians and Gynecologists.
- (W) "Gynecological health care provider" means a health care provider or health care facility that is primarily engaged in providing gynecological health care services.
- (X) "Health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by a health insurer to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.
- (Y) "Health care facility" means all institutions, whether public or private, proprietary or nonprofit, which offer diagnosis, treatment, inpatient or ambulatory care to two or more unrelated persons, and the buildings in which those services are offered. The term shall not apply to any facility operated by religious groups relying solely on spiritual means through prayer or healing, but includes all institutions included in 18 V.S.A. § 9432, except health maintenance organizations.

- (Z) "Health care provider" or "provider" means a person, partnership or corporation, other than a facility or institution, licensed or certified or authorized by law to provide professional health care services to an individual during that individual's health care, treatment or confinement.
- (AA) "Health care services" or "services" means services for the diagnosis, prevention, treatment, cure or relief of a health condition, illness, injury or disease.
- (BB) "Health insurer" means any health insurance company, nonprofit hospital and medical service corporation, managed care organization, and, to the extent permitted under federal law, any administrator of an insured, self-insured, or publicly funded health care benefit plan offered by public and private entities.
- (CC) "High volume provider" means either those providers whose member panels or member visits rank in the top twenty percent of the managed care organization's providers in the same specialty or subspecialty (e.g. – the 20% of primary care physicians with the highest number of visits or largest panel sizes), or those providers whose member panels or member visits are large enough to exceed a threshold determined by the managed care organization to be necessary for statistically meaningful interpretation of performance appraisal information (e.g. – primary care physicians with panels of 100 or more members).
- (DD) "Independent accreditation organization" means an organization recognized by the Department as qualified to review some or all of a managed care organization's quality management and consumer protection activities according to the criteria established in this rule.
- (EE) "Independent external review" means a review of a health care decision, by the Independent Panel of Mental Health Care Providers or an independent review organization pursuant to 8 V.S.A. §§4089a or 4089f, as applicable and as may be amended.
- (FF) "Manage health care delivery" means to apply any design or mechanism to a health benefit plan to affect access to or the quality, coordination or cost of the health care available to members under the health benefit plan, including but not limited to the use of any form of utilization management; pharmaceutical benefit management; networks, preferred providers or any other restrictions or incentives for members to use certain providers; and/or disease, care or case management.
- (GG) "Managed care organization" means any financing mechanism or system that manages health care delivery for its members or subscribers, including but not limited to health maintenance organizations, preferred provider organizations, exclusive provider organizations and any other health care delivery system or organization that manages health care delivery for its members or subscribers, or that issues a health insurance policy, plan, or subscriber contract which operates to manage health care delivery. The term managed care organization includes a mental health review agent as defined in 8

V.S.A. § 4089a, a health insurer as defined in 18 V.S.A. § 9402, a managed care organization as defined in 18 V.S.A. § 9402, a delegate of a health insurer or managed care organization, and any person or entity that meets the definition of a managed care organization under law.

- (HH) “Medical director” means a Vermont-licensed physician who is board-certified or board-eligible in his or her field of specialty as determined by the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA), and who is charged by a managed care organization with responsibility for overseeing all clinical activities of the health benefit plan, or his or her designee.
- (II) “Medical or scientific evidence” means the following sources:
1. Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.
 2. Peer-reviewed literature, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Excerpta Medica (EMBASE), Medline, and PubMed Medline, and resources from the Cochrane Library, HSTAT, and the National Guideline Clearinghouse.
 3. Medical journals recognized by the federal Secretary of Health and Human Services, under Section 1861(t)(2) of the federal Social Security Act.
 4. The following standard reference compendia: the American Hospital Formulary Service-Drug Information (AHFS Drug Information), the American Dental Association Accepted Dental Therapeutics and Monograph Series on Dental Materials and Therapeutics, The United States Pharmacopeia, The National Formulary and the USPDI.
 5. Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the Agency for Health Care Research and Quality, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Centers for Medicare and Medicaid Services, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.
 6. Peer-reviewed abstracts accepted for presentation at major medical association meetings.
- (JJ) “Medically appropriate off-label use of a drug” means the use of a drug, pursuant to a valid prescription by a health care provider, for other than the particular condition(s) for

which approval was given by the U.S. Food and Drug Administration in circumstances in which the medically appropriate off-label use is reasonably calculated to restore or maintain the member's health, prevent deterioration of or palliate the member's condition, prevent the reasonably likely onset of a health problem or detect an incipient problem; and that is informed by generally accepted medical or scientific evidence and consistent with generally accepted practice parameters as recognized by health care professions in the same specialties as typically provide the procedure or treatment, or diagnose or manage the medical condition.

- (KK) "Medically-necessary care" means health care services, including diagnostic testing, preventive services and aftercare, that are appropriate in terms of type, amount, frequency, level, setting, and duration to the member's diagnosis or condition. Medically-necessary care must be informed by generally accepted medical or scientific evidence and consistent with generally accepted practice parameters as recognized by health care professions in the same specialties as typically provide the procedure or treatment, or diagnose or manage the medical condition; must be informed by the unique needs of each individual patient and each presenting situation; and
1. help restore or maintain the member's health; or
 2. prevent deterioration of or palliate the member's condition; or
 3. prevent the reasonably likely onset of a health problem or detect an incipient problem.
- (LL) "Member" means any individual who has entered into a contract with a health insurer or managed care organization for the provision of health care services, or on whose behalf such an arrangement has been made, as well as the individual's dependents covered by the contract.
- (MM) "Mental health care provider" means any person, corporation, facility or institution certified or licensed by this state to provide mental health care or substance abuse services, including but not limited to a physician, a nurse with recognized psychiatric specialties, hospital or other health care facility, psychologist, clinical social worker, mental health counselor, alcohol or drug abuse counselor.
- (NN) "Mental health condition" means any condition or disorder involving mental illness or alcohol or substance abuse that falls under any of the diagnostic categories listed in the mental disorders section of the international classification of disease, as periodically revised.
- (OO) "Mental health professional" means any person, certified or licensed by this state to provide mental health care services, including but not limited to a physician, a nurse with recognized psychiatric specialties, psychologist, clinical social worker, mental health counselor, alcohol or drug abuse counselor.

- (PP) "Peer review committee" means a committee as defined in 26 V.S.A. § 1441, and for purposes of this rule includes any quality management, credentialing or other similar committee established by a managed care organization pursuant to 18 V.S.A. § 9414(c)(1) and this rule.
- (QQ) "Person" means a natural person, partnership, unincorporated association, corporation, limited liability company, municipality, the state of Vermont or a department, agency or subdivision of the state, or other legal entity.
- (RR) "Pharmaceutical benefit management program" ("PBMP") means any mechanisms or procedures used to manage prescription drug benefits, including but not limited to formularies, dose restrictions, prior or other authorization requirements, step therapy and/or substitution requirements.
- (SS) "Post-service Review" means review of any claim for a benefit that is not a pre-service or concurrent review claim as defined by this rule.
- (TT) "Pre-service Review" means review of any claim for a benefit with respect to which the terms of coverage condition receipt of the benefit, in whole or in part, on approval of the benefit in advance of obtaining health care.
- (UU) "Primary care provider" means a health care provider who, within that provider's scope of practice as defined under the relevant state licensing law, provides primary care services, and who is designated as a primary care provider by a managed care organization.
- (VV) "Primary care services" include services provided by providers specifically trained for and skilled in first-contact and continuing care for persons with undiagnosed signs, symptoms or health concerns, not limited by problem origin (biological, behavioral or social), organ system or diagnosis. Primary care services include health promotion, disease prevention, health maintenance, counseling, patient education, self-management support, care planning and the diagnosis and treatment of acute and chronic illnesses in a variety of health care settings.
- (WW) "Primary verification" means verification of a health professional's credentials based upon evidence obtained from the issuing source of the credential.
- (XX) "Provider Directory" means a comprehensive list of all of the health care providers employed by, under contract or subcontract with, in a network, designated as preferred or otherwise in an arrangement with the managed care organization and available to members or subscribers of a particular health benefit plan.
- (YY) "Provider List" means a subset of the provider directory created by the managed care organization to meet a particular member's health care and geographic accessibility needs, usually generated in response to a request from the member or the member's representative.

- (ZZ) "Quality management program" means a set of procedures and activities designed to safeguard or improve the quality of health care and the quality of the managed care organization's service to members and providers by assessing the quality of care or service, usually against a set of established standards, and taking action to improve it.
- (AAA) "Quality improvement" means the effort to improve the quality of health care services and outcomes of treatment for members as well as the quality of the managed care organization's service to members and providers. Opportunities to improve care and service are found primarily by continual examination of, and continual feedback and education about how services are provided and the results they produce.
- (BBB) "Quality of care" means the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes, decrease the probability of undesired health outcomes, and are consistent with current professional knowledge.
- (CCC) "Referral" means a prior authorization from the managed care organization or contracted provider that allows a member to have one or more appointments with a health care provider for consultation, diagnosis, or treatment of a medical condition, to be covered as a benefit under the member's health benefit plan contract.
- (DDD) "Relevant document, record or other information" means, for the purposes of Section 3.3, that a document, record or other information shall be considered relevant if such document, record or other information was relied upon in making the benefit determination or the determination of a grievance, or was submitted, considered or generated in the course of making the benefit determination or the determination of a grievance, without regard to whether such document, record or other information was relied upon in making the benefit determination or the determination of a grievance.
- (EEE) "Secondary verification" means verification of a health professional's credentials based on evidence obtained by means other than direct contact with the issuing source of the credential.
- (FFF) "Service area" means the geographic region in or for which a health benefit plan subject to Part 5 or 6 of this rule is, consistent with applicable law, marketed, sold, intended by the issuer and described in the policy and certificate as the region in which the travel and waiting time standards in Section 5.1 of this rule are met and in which certificate holders are expected to and are able to access all or most of the covered benefits at the benefit level most advantageous to the member. That a health benefit plan subject to Part 5 or 6 of this rule may be required to authorize coverage for services for individual members in a location outside of the service area at the benefit level most advantageous to the member does not subject that location to the travel and waiting time requirements of this rule.
- (GGG) "Stabilize" means, with respect to an emergency medical condition, to provide such medical treatment to the member as may be necessary to assure, within reasonable

medical probability, that no material deterioration of the condition is likely to result from discharge or to occur during transfer.

- (HHH) "Step therapy" means a type of protocol that specifies the sequence in which different prescription drugs are to be tried for treating a specified medical condition.
- (III) "Urgently-needed care" or "urgent care" means those health care services that are necessary to treat a condition or illness of an individual that if not provided promptly (within twenty-four hours or a time frame consistent with the medical exigencies of the case) presents a serious risk of harm.
- (JJJ) "Utilization management" means the set of organizational functions and related policies, procedures, criteria, standards, protocols and measures used by a managed care organization or pharmaceutical benefit management program to ensure that it is appropriately managing access to and the quality and cost of health care services, including prescription drug benefits, provided to its members.
- (KKK) "Utilization review" means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings, including prescription drugs.
- (LLL) "Utilization review guidelines" mean the normative standards and clinical review criteria for resource utilization for various clinical conditions and medical services that are used by managed care organizations in deciding whether to approve or deny health care services.

1.5 Confidentiality of Quality Management and Peer Review Information.

- (A) Except as otherwise required by 18 V.S.A. § 9414, each managed care organization shall take the appropriate steps necessary to ensure that information gathered by it in its peer review and quality management activities, including those conducted in relation to credentialing, recredentialing and associated monitoring, shall be maintained as confidential and privileged.
- (B) Peer review, quality management and other similar information made available to the Department or other designated organizations under 18 V.S.A. § 9414(f)(2) shall be furnished in a manner that does not disclose the identity of individual patients, health care providers or other individuals, unless otherwise specified by the Department.
- (C) The minutes or records of the peer review or quality management committee formed under Parts 5 or 6 of this rule are confidential and privileged under 26 V.S.A. § 1443, except as otherwise provided in 18 V.S.A. § 9414(f)(2) and this rule.
- (D) The Department's confidentiality code shall apply to the collection and review of information by the Department or its designated organization under 18 V.S.A. § 9414 and this rule.

- (E) Peer review, quality management and other similar information disclosed to the Department pursuant to this rule shall be confidential and privileged and shall not be subject to subpoena or available for public disclosure, except as otherwise required by 18 V.S.A. § 9414 or this rule.
- (F) The Department is authorized to use any information gathered in the course of its review, including confidential or privileged information, in the course of any legal or regulatory action against a managed care organization. Information used in a legal or regulatory proceeding that is required to be kept confidential, including the records of the peer review or quality management committee designated under Parts 5 or 6 of this rule, shall be filed with the court or appropriate administrative body under seal and shall not be available for public disclosure.

1.6 Compliance Assessment and Review Generally.

- (A) The Department in its sole discretion may assess and review the performance of managed care organizations not otherwise subject to Part 6 of this rule by:
 - 1. applying all or part of the annual and/or periodic filing and/or review requirements in Part 6 to a managed care organization subject to this rule but not otherwise subject to Part 6, with at least one year's notice from the Department to the managed care organization; or
 - 2. assessing data, reports, inquiries, complaints, independent external review requests and other information available to or requested by the Department. In exercising this discretion, the Department may consider factors such as but not limited to the nature and extent of care management mechanisms or financial incentives used, baseline performance, performance over time, accreditation status, anticipated changes in the number of covered lives and/or any other information regarding the managed care organization, the affiliated mental health review agent and any delegates of these organizations.
- (B) Compliance assessment and enforcement with respect to delegates, except for mental health review agents subject to Part 6 of this rule, that manage health care delivery for members or subscribers of any comprehensive major medical health benefit plan subject to the Department's jurisdiction may be conducted through the Department's assessment of the delegating entity, subject to the Department's discretion. The Department may determine that direct examination of a delegate is warranted and may elect to directly assess compliance and/or commence enforcement action against a delegate based on factors such as but not limited to the number of Vermont members affected, data and reports regarding the delegate's performance, and the volume and severity of complaints regarding the delegate.
- (C) The Department may at any time conduct an evaluation of a managed care organization's performance in specific areas of operations. Such focused reviews may be performed in response to periodic review findings, a complaint or grievance, a pattern of complaints or

grievances, or other information that has come to the attention of the Department. The Department shall advise the managed care organization of the specific areas of operations that will be the subject of the review and the statutory or regulatory provisions under examination. This review will be carried out through the assessment of documentation submitted by the managed care organization as required by this rule and by review of any other records or other examination as deemed necessary by the Department, and may include an on-site review of the managed care organization and/or its delegate.

- (D) The Department may, in its discretion, designate another organization to review baseline, annual, periodic or other filings and to conduct baseline, periodic or focused reviews of a managed care organizations. Any such organization shall have a confidentiality code acceptable to the Department, or shall be subject to the Department's confidentiality code. The Department shall notify a managed care organization of the identity of such an organization before commencing the evaluation.
- (E) The Department in its capacity as a health oversight agency pursuant to federal law and as authorized by 18 VSA § 9414 or its designated organization may examine and review information protected by the patient's privilege established in 12 V.S.A. § 1612(a) or otherwise required by law to be held confidential.
 - 1. Notwithstanding the provisions of 26 V.S.A. § 1443, the Department or its designated organization shall have reasonable access to the minutes or records of the managed care organization's peer review, quality management and any other committee for the sole purpose of reviewing the managed care organization's compliance with this rule and other applicable law.
 - 2. Records or minutes of the peer review, quality management and any other committees reviewed by the Department or its designated organization under this section shall not disclose the identity of patients, health care providers or other individuals.
- (F) The Department may examine and review the data reported or required to be reported to the Department under Titles 8 or 18 of the Vermont Statutes Annotated, this rule and any other applicable rule, as well as examine and review the methodologies used by the managed care organization to compute measures used by the managed care organization to comply with such laws or rules.
- (G) The Department or its designated organization shall prepare and keep on file a written report summarizing the scope of its review, its findings, its recommendations for improvement and determinations regarding areas of non-compliance, if any. If prepared by an organization designated by the Department, the written report shall include findings and recommendations for improvement. The Department shall review the report and shall make a final determination on the findings, recommendations for improvement and determinations regarding areas of non-compliance, if any.

- (H) In addition to making a determination under paragraph (G) of this subsection, the Department may require a managed care organization to amend or modify its quality management program or other programs or activities in order to comply with this rule and other applicable law. Failure of the managed care organization to comply with the requirement shall be deemed a violation of law.
- 1.7 Implementation Manual. The Commissioner may issue from time to time an Implementation Manual, designed to provide guidance to interested parties concerning the Department's interpretation of the laws and regulations which are the subject matter of this Rule.
- 1.8 Payment for Baseline, Annual, Periodic and Focused Compliance Reviews.
- (A) Each managed care organization subject to examination, investigation or review by the Department under 18 V.S.A. § 9414 and this rule shall pay the Department the reasonable costs of such activities in an amount to be determined by the Commissioner.
- (B) A managed care organization shall pay the costs due under this subsection within thirty (30) days of receipt of an invoice from the Department.
- (C) Failure of a managed care organization to pay any costs assessed under 18 V.S.A. § 9414(h) and this rule is a violation of Vermont law and shall be subject to any and all sanctions allowed by law.
- 1.9 Coordination With Other Relevant State Functions. If any department of the Agency of Human Services is designated by statute to conduct activities that specifically relate to any function of a managed care organization specified in this rule, the Commissioner, in the Commissioner's sole discretion, may accept all or part of the agency's assessment of the managed care organization's compliance with requirements pertaining to that function, in whole or in part.
- 1.10 Enforcement. The Department has the power and responsibility to ensure that each managed care organization acts in accordance with applicable law. In exercising this jurisdiction, the Department may use any or all of the powers granted to it under Title 8 of the Vermont Statutes Annotated and Chapter 221 of Title 18 of the Vermont Statutes Annotated in the course of monitoring, investigating or otherwise ensuring compliance by managed care organizations with the requirements of this regulation and any other applicable law or regulation. Approval of a filing or review does not preclude investigation and/or enforcement action by the Department if indicated.
- 1.11 Severability. If any provision of this rule or the application thereof to any person or circumstance is for any reason held to be invalid, the remainder of the rule and the application of such provisions to other persons or circumstances shall be not affected thereby.
- 1.12 Effective Date. This rule shall take effect upon adoption, with the following exceptions:
- (A) Handbooks and forms that require revision as a result of Sections 2.2, 4.1 and any other provisions of this rule shall be filed with the Department for approval prior to use

consistent with 8 V.S.A. § 4062 no later than six (6) months from the date of adoption of this rule.

- (B) Plans for compliance with the components of Sections 2.2 and 4.1 of this rule that require modifications to the collection, display or dissemination of provider directory or pharmaceutical benefit information shall be submitted to the Department for review and approval prior to implementation no later than six (6) months from the date of adoption of this rule.
- (C) Plans for compliance and associated letters and notices related to Sections 3.2 and 3.3 of this rule shall be submitted to the Department for review and approval prior to implementation no later than six (6) months from the date of adoption of this rule.
- (D) Full compliance with the provisions of this rule that are referenced in paragraphs (A), (B) and (C) of this subsection is expected on the date specified in the Department's approval of the related form filings and other submissions.
- (E) To the extent that Sections 5.2, 5.3, 5.4, 6.2 or 6.3 of this Rule impose requirements on managed care organizations that the Department determines were not in effect prior to the Rule's adoption, each managed care organization shall have one year from the date of adoption to come into compliance with such new requirements.
- (F) The Department may, in its sole discretion and upon good cause shown, permit a managed care organization to transition to full compliance with any component(s) of this rule over a period of time not to exceed eighteen months from the date of adoption.

PART 2: BASIC CONSUMER PROTECTIONS REQUIRED OF ALL MANAGED CARE ORGANIZATIONS

- 2.1 Maintenance of Health Care Information; Confidentiality Procedures. Each managed care organization shall establish and implement policies, standards and procedures to protect the confidentiality, security and integrity of individually-identifiable health care information in its possession or used by it in order to ensure that the information is not negligently, inappropriately or unlawfully disclosed. For purposes of this section, "individually-identifiable health care information" means any data or information, whether oral or recorded, in any form or medium, that identifies an individual or can reasonably identify an individual by reference to publicly-available information; relates to the individual's health history, health care or health status; and is obtained by or from a health care provider, a health care facility, a health insurer, or an employer. These policies, standards and procedures shall include:
- (A) the use of nondisclosure and confidentiality policies and agreements, which shall include guidelines for access to health care information on a need-to-know basis only, and safeguards to enforce those guidelines;
 - (B) periodic training for all employees as to the policies, standards and procedures established under this provision, applicable state or federal laws or regulations as to the

- confidential handling of health care information, and any related licensing rules or professional ethical standards;
- (C) disciplinary measures for violations of the managed care organization's confidentiality policies, standards or procedures;
 - (D) the identification of individuals who are authorized to disclose individually-identifiable health care information;
 - (E) methods for handling, disclosing, storing and disposing of individually-identifiable health care information, including procedures for appropriate responses to court-ordered legal process, legal or regulatory process from a governmental entity or legal process issued by an attorney; and
 - (F) if the managed care organization is an employer of or contracts with the individual whose information is being collected or used for health care services purposes, policies, standards and procedures to ensure that the individual's health care information is maintained separately and apart from the individual's other records and is used only for the lawful health care purposes for which the information was acquired.

2.2 Disclosure of Information.

- (A) Policy Forms, Certificates and Handbooks: Each managed care organization that issues, is the plan administrator for or is a delegate responsible for the plan documents specified below that relate to a comprehensive major medical health benefit plan subject to the Department's jurisdiction shall ensure that the policy form or certificate, and handbook if used, are approved by the Department prior to use and meet the following requirements in addition to any other requirements specified by the Department:
 1. The text shall be in at least eleven-point font in hard copy; in plain language at no greater than an eighth grade reading level, or less if required by other law; shall be organized in a way that is visually easy to read and use; and shall include a table of contents and a definitions section. The Department, in its sole discretion, may waive the eighth grade reading level requirement for parts of the text for good cause shown.
 2. The documents shall be made available in hard copy, on the internet and in a format suitable for electronic mailing; provided to each member in the format requested upon enrollment and upon any changes thereafter; and shall also be made available upon request to prospective members prior to enrollment. A managed care organization may satisfy the requirements of this section by giving a copy of the approved policy form and the handbook, if used, to each subscriber rather than to each individual member. Information shall be provided to members regarding how to obtain necessary translation or interpretation of the document.
 3. At least the following information shall be contained in the policy form or certificate and, if a handbook is used, in the handbook:

- a. The health benefit plan's coverage provisions, including a clear description of the service area, if applicable, health care benefits, benefit maximums, benefit limitations, exclusions from coverage (including procedures deemed experimental or investigational by the managed care organization), restrictions on referral or treatment options, requirements for prior authorization, utilization review, notification of hospital admission or other member obligations to notify the managed care organization, the use of formularies, and any other limitations on the services covered under the member's enrollment plan. All plan materials, including a handbook if one is used, shall clearly explain the legal effect of each plan document.
- b. If prior authorization or utilization review is required before obtaining treatment or services, the process a member must use to obtain that authorization or review, including any time lines that apply and how to obtain an expedited review.
- c. The financial inducements offered to any health care provider or health care facility for the reduction or limitation of health care services. Nothing in this paragraph shall be construed to require disclosure of individual contracts or the specific details of any financial arrangement between a managed care organization and a health care provider unless otherwise required by law.
- d. The member's responsibility for payment of premiums, coinsurance, co-payments, deductibles and any other charges, annual limits on a member's financial responsibility, caps on payments for covered services, and the member's financial responsibility for non-covered procedures, treatments or services.
- e. The member's financial responsibility for payment when services are provided by a health care provider who is not a contracted provider with the managed care organization, as applicable, or by any provider after an adverse benefit determination by the managed care organization.
- f. A description of the grievance process used to resolve disputes between a member and the managed care organization, and how the member can access that process.
- g. A summary of the managed care organization's quality management program.
- h. An explanation that emergency services do not require prior authorization; that coverage for emergency services outside of the service area will be the same as for emergency services within the

service area; that it is the responsibility of the managed care organization or health insurer to respond to, defend against and resolve any request or claim by a non-contracted provider of emergency services for payment exceeding the amount it was paid or reimbursed by the member's managed care organization or health insurer; and the point of contact at the managed care organization or health insurer for a member who receives any such request or claim.

- i. How members seeking information or authorization can contact the appropriate department or staff member of the managed care organization.
- j. How the member may obtain the most current provider directory and provider lists in a manner and format readily accessible to the member.
- k. The process for selecting primary care providers (if selection is encouraged or required) and for obtaining access to other providers under contract with the managed care organization, including any restrictions on the use of contracted specialists.
- l. The procedure for changing primary and specialty care providers under contract with the managed care organization, including any restrictions on changing providers, where applicable.
- m. How members can obtain standing referrals to contracted specialists, or use specialists or specialized facilities to provide and coordinate their primary and specialty care pursuant to the requirements of this rule, where applicable.
- n. The waiting time and travel time standards established by this rule.
- o. Opportunities for member participation in the development of managed care organization policies and in the managed care organization's quality management activities.
- p. Information regarding consumer information and services, including local and toll-free consumer or member services telephone numbers for the managed care organization, the Department and the Vermont Office of Health Care Ombudsman, with an explanation of each organization's respective role.
- q. A list of all information available to the member upon request, as required by this rule.
- r. If the managed care organization manages pharmaceutical benefits, the disclosure shall also explain in a clear and prominent manner that

pharmaceutical benefit management with respect to particular drugs may change frequently; and how and where members and providers can access the primary source of up-to-date pharmaceutical benefit information, including but not limited to lists of the specific drugs subject to pharmaceutical benefit management; whether, how and under what conditions a particular drug is or is not covered by the plan; and the process by which grievances and exceptions to pharmaceutical benefit management decisions may be made.

- (B) Provider Directories and Lists: Provider directories related to a comprehensive major medical health benefit plan subject to the Department's jurisdiction shall be made available to any member or prospective member upon request and shall meet the following requirements, as applicable:
1. Provider directories shall be available on the Internet and made available upon request in hard copy and in a format suitable for electronic mailing. The provider directory may be separate from the policy form or handbook if the policy form or handbook clearly indicates how the member or prospective member can access the most up-to-date version of the directory.
 2. Provider directories shall:
 - a. be updated, audited and corrected (by addendum or otherwise) at least once every six (6) months by the managed care organization, and shall be updated whenever new information is submitted by providers;
 - b. include, and internet directories shall be searchable by, provider name, geographic region, provider specialty and, for facilities, by facility type;
 - c. include provider names, telephone numbers, and addresses; and
 - d. in the case of physicians, include information about board certification, and in the case of primary care providers, indicate whether they are accepting new patients.
 3. Provider directories shall indicate at least the following practice limitations if reported by contracted providers: limitations as to patient age groups and specific conditions. This requirement shall not be construed to require indication of practice limitations that are evident based on a provider's specialty.
 4. Provider directories shall explain that the member (and/or the member's representative) may obtain active assistance from the managed care organization to locate a provider, from a clinical representative if preferred and requested. For the purposes of this subsection, "active assistance" shall include but not be limited to generating a provider list; assisting members in identifying providers who are qualified to deliver the type of care being sought, who are currently

taking new patients, and who provide services that are generally considered to be covered benefits; and facilitating appointments with providers if such assistance is required. Provider directories shall explain that the member should contact the managed care organization if the member has been unable to locate a provider using the list or with assistance previously provided.

5. If a case or care management or chronic care program is available, the provider directory shall explain the benefits of participation and how the member may obtain the service or shall reference the plan documents that contain this information.
6. Provider directories shall explain that coverage is not guaranteed until the requirements for utilization review have been completed and documentation of authorization has been issued. Such explanation shall include a description of or reference to certificate or handbook provisions that explain how to seek authorization; how to seek authorization if the member (and/or the member's representative) believes the necessary care is not available from contracted providers; how to initiate a grievance if coverage has been denied, reduced, modified or terminated; and the potential consequences if authorization is not obtained.
7. Provider directories shall also, with respect to mental health and substance abuse services:
 - a. explain in a clear and prominent manner that a given provider's availability to new patients may change frequently;
 - b. clearly indicate when there are program, clinic or similar organizationally-based requirements that limit or prevent general plan membership from directly accessing a provider practicing in such a setting. In such cases, the directory shall list the program, clinic or organization name above or together with the individual provider's name, and shall list the relevant intake phone number and address. If the provider has a separate practice that may be accessed directly by general plan membership, that practice shall be listed separately;
 - c. explain that any provider of mental health or substance abuse services not currently under contract with the managed care organization that is willing to meet the terms and conditions for participation may apply for contracted status and may become contracted after successful completion of credentialing; and
 - d. in addition to being updated, audited and corrected whenever new information is submitted by providers, be updated based on current information from individual contracted providers that is obtained in

response to active solicitation by the managed care organization at least once every six (6) months.

8. Provider lists shall contain the health care and geographic information requested by the member and be provided telephonically, in hard copy or in a format suitable for electronic mailing, whichever is requested by the member.

(C) Oral and Written Communications With Members:

1. Managed care organizations shall ensure that all communications in response to inquiries regarding access to and reimbursement for covered services explain to the member or person contacting the managed care organization on the member's behalf, unless clearly not applicable:
 - a. that coverage and the extent and level of coverage are governed by the plan documents and are not guaranteed until all requirements for utilization review and grievance, if relevant have been completed and documentation of authorization has been issued;
 - b. how documentation of the authorization, including the extent and level of coverage, will be issued; and
 - c. when applicable, that a member may be billed by a non-contracted provider(s) for any balance between the provider's charges and the amount paid by the health benefit plan. Whether or not in response to an inquiry, all communications to a member regarding payment or reimbursement for emergency services rendered by a non-contracted provider shall include clear notice that it is the responsibility of the managed care organization or health insurer to respond to, defend against and resolve any request or claim by a non-contracted provider of emergency services for payment exceeding the amount it was paid or reimbursed by the member's managed care organization or health insurer; and shall include information regarding the point of contact at the managed care organization or health insurer for a member who receives any such request or claim.
2. Managed care organizations shall meet the following additional requirements with respect to communications regarding mental health and substance abuse services:
 - a. The managed care organization shall explain that the member (and/or the member's representative) may obtain active assistance from the managed care organization, including from a clinical representative if preferred and requested, to locate a provider list that will assist them in identifying providers who are qualified to deliver the type of care being sought, are

currently taking new patients, and provide services that are generally considered to be covered benefits;

- b. The managed care organization shall explain that if a member wishes to access a provider of mental health or substance abuse services not currently under contract with the managed care organization, a provider willing to meet the terms and conditions for participation may apply for contracted status and may become a contracted provider after successful completion of credentialing;
 - c. In the case of any inquiry or request for a provider list regarding a level of mental health or substance abuse care more intense than office-based outpatient services or that otherwise indicates an urgent, medically complex or unique situation related to mental health or substance abuse, the managed care organization shall transfer the member to a clinical representative of the managed care organization for assistance; and
 - d. When a clinical representative response is required under paragraphs a, b, or c of this subsection, the representative shall offer assistance, as appropriate, to initiate utilization management and, if relevant, inform the person making the inquiry whether a relevant case management or chronic care program is available, the benefits of participation and how the member may obtain the service.
3. The managed care organization shall maintain evidence of compliance with the requirements of this section for all of its communications with or on behalf of members. Failure to produce evidence of compliance shall result in a presumption favoring the member's position in the event of an internal grievance and any complaint to or enforcement action by the Department.

2.3 Access To and Continuity of Care: Generally.

- (A) Managed care organizations shall ensure that their policies and procedures facilitate the provision of health care services to their members in a manner informed by generally accepted medical or scientific evidence consistent with prevailing standards of medical practice as recognized by health care professions in the same specialties as typically provide the procedure or treatment, or diagnose or manage the medical condition, and shall take into account the unique needs of each individual patient and each presenting situation.
- (B) Each managed care organization shall ensure timely access to effective, medically necessary care and shall monitor and take action, as necessary, to improve coordination and continuity of care for its members across service providers. For purposes of this section, "coordination and continuity of care" means that a member's health care services are managed by the managed care organization(s) in a manner that facilitates

collaborative and effective treatment of a condition, illness or other medical condition, including but not limited to ensuring that the managed care organization:

1. manages the benefits available for treatment of mental health and substance abuse conditions in a manner that allows for the effective provision of medically necessary care in urgent, medically complex, and unique situations, including but not limited to situations involving children and adolescents;
2. has authorized covered benefits necessary for a medically safe and appropriate discharge or transition plan developed after consultation with the treating health care provider or the provider's designee before the managed care organization renders a decision that will result in discharge or transfer from a facility; and
3. collaborates with health care providers to monitor and improve coordination between mental health and other health care.

2.4 Access To and Continuity of Care: Emergency and Urgent Services.

- (A) Each managed care organization shall ensure that its members have access to emergency services twenty-four (24) hours per day, seven (7) days per week inside the health benefit plan's service area, and coverage for such services whether the member is inside or outside the health benefit plan's usual service area at the time such services are needed.
- (B) If a prudent layperson or provider would have believed that an emergency medical condition existed, a managed care organization shall cover emergency services provided in a hospital or other medically appropriate setting necessary to evaluate, stabilize and provide medically necessary emergency transport for a member. A managed care organization shall not require prior authorization of such services or the use of contracted providers. Coverage for the member shall be consistent with the terms and conditions for coverage of services obtained from a contracted provider within the service area whether or not the emergency services were obtained from contracted providers within or outside of the health benefit plan's service area. There shall be no additional liability to the member. The liability of a managed care organization or health insurer to a non-contracted provider for emergency services rendered to a member shall be limited to the reasonable and customary value for the health care services rendered, except that it shall be the responsibility of the managed care organization or health insurer to respond to, defend against and resolve any provider request or claim for payment exceeding the amount it paid or reimbursed the provider pursuant to this subsection. Nothing in this section shall be construed to prohibit a managed care organization from:
 1. holding members financially responsible pursuant to the terms of the insurance policy or certificate if they obtain services that do not meet the definition of "emergency services" set forth in this rule;

2. advising members that they may contact the managed care organization in advance to ascertain whether the presenting condition meets the definition of "emergency medical condition" set forth in this rule;
 3. requiring a contracted provider or facility to contact the managed care organization to initiate utilization review within twenty-four (24) hours of an emergency admission; or
 4. if the health benefit plan makes such notification an obligation of the member, or in the event of admission to a facility not under contract with the managed care organization, requiring member contact to initiate utilization review within twenty-four (24) hours of admission or as soon after admission as is reasonably possible for the member.
- (C) A managed care plan shall cover emergency services if the managed care organization, acting through a contracted provider or through any other authorized representative, has authorized the provision of emergency services. In the event such authorization has been given or obtained, the managed care organization shall not subsequently retract its authorization after the emergency services have been provided, or reduce payment for an item or service furnished in reliance on the authorization, unless the authorization was based on a material misrepresentation about the member's health condition made by the member or by the provider of emergency services.
- (D) Coverage of emergency services shall be subject to applicable copayments, coinsurance and deductibles.
- (E) Each managed care organization shall ensure that its members have access to urgently-needed care as defined in this rule inside the health benefit plan's service area, and coverage for such services whether the member is inside or outside the health benefit plan's usual service area at the time such services are needed.
- 2.5 Grievance Procedures for Managed Care Organizations Not Subject to Part 3. A managed care organization that does not use or administer utilization management mechanisms and that is therefore not subject to Part 3 of this rule shall have a review process available to address and resolve member grievances that meets the timeframes and other applicable requirements in Section 3.3 of this rule.

PART 3: ADDITIONAL REQUIREMENTS IF UTILIZATION MANAGEMENT MECHANISMS ARE USED

3.1 General Requirements for Utilization Management Programs.

- (A) Each managed care organization shall be responsible for monitoring all utilization management activities carried out by it or on its behalf and for ensuring that all requirements of this rule and other applicable laws and rules are met.

(B) A managed care organization that conducts utilization management shall implement a written utilization management program that describes all utilization management activities, both delegated and non-delegated, for services provided to members. The program document shall describe, and, where applicable, the managed care organization shall ensure implementation of, the following:

1. Procedures to evaluate whether the requested service is a covered benefit. In the case of new technology, services or treatment; or new application of existing technology, services or treatment, the managed care organization shall have a mechanism to evaluate its inclusion in the benefit package based on reviews of information from appropriate bodies, using professionals with appropriate specialty expertise in the new technology, services, or treatment and including consideration of determinations made by independent review organizations pursuant to 8 V.S.A. §4089f;
2. Procedures to evaluate the medical necessity, appropriateness, efficacy or efficiency of health services;
3. The data sources and utilization review guidelines used in utilization management;
4. The process by which individual clinical case data, assessments and information are used together with utilization review guidelines during pre-service, concurrent and post-service reviews in making decisions to approve or deny requested health care services;
5. The process for conducting reviews of adverse determinations;
6. Mechanisms to ensure the consistent application of utilization review guidelines and consistency in decisions such that, within the scope of coverage limits, decisions are compatible with the definition of “medically necessary care” in this rule and with the unique needs of each individual patient and each presenting situation. The mechanisms shall include annual training in utilization review guidelines and annual accuracy and interrater reliability testing for and with all reviewers;
7. The data collection processes and analytical methods used in assessing the utilization of health care services by members;
8. Provisions for ensuring the confidentiality of clinical and proprietary information;
9. The organizational structure (for example, utilization management committee, quality management committee, or other committee) that periodically assesses

utilization management activities and reports to the managed care organization's governing body; and

10. The staff position functionally responsible for the day-to-day management of the utilization management function.

(C) Each managed care organization's utilization management program shall use documented utilization review guidelines that are informed by generally accepted medical and scientific evidence and consistent with clinical practice parameters as recognized by health care professions in the same specialties as typically provide the procedure or treatment, or diagnose or manage the medical condition. The managed care organization shall demonstrate to the satisfaction of the Commissioner that the utilization review guidelines have been periodically reviewed and updated, taking into account input from practicing physicians and other health care providers, including providers under contract with the managed care organization, if any. Relevant utilization review guidelines shall be made available to all providers under contract with the managed care organization, if any, and shall be made available to members and any of their treating providers upon request. With respect to utilization review guidelines for services related to mental health and/or substance abuse conditions and disorders, the Commissioner may consult with the Vermont Department of Health, the Vermont Department of Mental Health and/or other clinical experts in mental health and substance abuse conditions and disorders in assessing compliance with this subsection. This subsection shall not be construed to require managed care organizations to make modifications to nationally-recognized guidelines based on input from their contracted providers.

(D) Utilization management mechanisms shall:

1. not deter timely access to or compromise the effectiveness of medically necessary care for any condition;
2. not result in any compromise to a member's safety;
3. be of a nature, frequency and periodicity that is clinically reasonable in view of the diagnosis or condition generally, the nature of the service(s) under review and, with respect to concurrent review or other review during an ongoing course of treatment, that takes into account the member's past history, current condition and progress during the course of treatment; and
4. take into account and make reasonable accommodations when a member's condition impacts the member's ability to follow utilization management procedures.

(E) In addition to the other requirements in this part, utilization management mechanisms applied to mental health and/or substance abuse benefits shall:

1. be prospective or concurrent with the treatment unless otherwise requested by a member or his/her representative, or by a provider on behalf of a member;
 2. not result in an adverse benefit determination until the reviewer has directly communicated with the member's treating mental health provider or the treating mental health provider's designee, unless the treating provider or designee has refused or repeatedly failed to engage in such communication when it has been offered at a time and in a manner reasonably convenient to the provider;
 3. ensure that any adverse benefit determination shall include the evaluation, findings, and concurrence of a Vermont-licensed mental health professional whose training and expertise is at least comparable to that of the treating provider;
 4. be designed to allow a member to initiate a course of outpatient mental health or substance abuse treatment by directly accessing a contracted provider for a minimum of two visits without the member being required to initiate utilization management or provide notice to the managed care organization;
 5. be based on the complexity of the individual case and shall not require greater burden to the member or the treating health care provider than would be required for utilization management of similar benefits, including but not limited to requiring additional steps on the part of the member or provider, or requiring a greater investment of time by the member or provider in fulfilling requirements for utilization management; and
 6. take into account and be tailored to at least the following factors: the patient's clinical acuity; intoxication and/or withdrawal potential; biomedical, mental health and/or substance abuse co-morbidities; functional status; relapse potential; treatment and recovery history; and assessment of coping skills in view of the anticipated recovery environment.
- (F) Each managed care organization shall have a registered nurse or physician and, for mental health and substance abuse utilization management, a qualified licensed mental health care provider readily available by telephone seven (7) days a week, twenty-four (24) hours each day, to render utilization review determinations to members and treating providers.
- (G) With regard to utilization management determinations, each managed care organization shall ensure that:
1. Individual clinical case assessments and clinical data reported by the treating provider are given equal or greater weight than utilization review guidelines in making decisions to approve or deny care, with the former taking precedence over the latter when there is a conflict between the two.

2. All determinations to deny, limit, reduce, terminate or modify an admission, service, procedure or extension of stay are rendered by a physician under the direction of the medical director responsible for medical services provided to the managed care organization's members, except when the denial is based on eligibility for coverage or is a denial of a service that is clearly excluded from coverage and that could not in any way be considered an appealable decision pursuant to 8 VSA §4089f or any other Vermont laws or rules regarding independent external review.
3. If services that require prior authorization have been authorized and the services are either currently being provided to a member in a health care facility or are another type of ongoing course of treatment and the treating provider has determined that it is medically necessary for the ongoing course of treatment to continue without disruption or delay, the services shall continue to be covered until:
 - a. the exhaustion of all internal expedited grievances, if requested within twenty-four (24) hours of receipt of the denial(s); or until the independent external review decision is issued, if expedited independent external review is requested within twenty-four (24) hours of the receipt of the final grievance decision and notice of appeal rights by the member and is conducted in accordance with the time frames specified by law; and
 - b. the managed care organization has authorized coverage for a medically safe and appropriate discharge or transition plan developed after consultation with the member's treating health care provider or the treating health care provider's designee. For purposes of this subsection, a treating health care provider may select a hospital discharge planner as his or her designee.
4. If the denial is upheld by an independent external review conducted pursuant to Vermont law, the managed care organization is not responsible for payment for the services that were the subject to the independent external review beyond the date the independent external review decision is issued. If the member nonetheless elects to continue the current level of treatment, the managed care organization may require that the member or treating provider contact the managed care organization in advance of discharge for the purpose of initiating utilization management regarding the discharge plan described in Subsection 3.b. above.
5. Except in cases where there was material misrepresentation or fraud, the managed care organization shall not retroactively deny or limit reimbursement for the services described below. Nothing in this subsection prohibits managed care organizations from requiring utilization management mechanisms permitted by law or from communicating those requirements to members.

- a. A covered service the managed care organization determines, either upon receipt of the claim or upon grievance review, to have been medically necessary but the member failed to fulfill the member's obligation to obtain prior authorization. If the managed care organization chooses to issue an initial administrative denial when a member fails to obtain prior authorization, it shall also provide the member with clear notice that coverage will be provided if the managed care organization finds the service to be covered and medically necessary during grievance review. This subsection does not apply to a provider's obligation. Nothing in this subsection shall be construed to relieve a contracted provider from its obligation to comply with the managed care organization's utilization management mechanisms or to relieve a contracted provider of the consequences for failure to comply with such mechanisms;
 - b. Any covered service provided to an eligible member by a provider who relied upon the written or oral authorization of the managed care organization or its agents prior to providing the service to the member; or
 - c. A covered service provided to a member by his or her primary care provider or another contracted provider who relied upon the written or oral referral of the primary care provider when the health benefit plan requires primary care physician referrals for members to use specialists.
- (H) Each managed care organization shall routinely assess the clinical and cost outcomes of its utilization management program, measure provider satisfaction with the utilization management program, and identify opportunities to improve provider satisfaction with the utilization management program.
- (I) Each managed care organization shall have a data system sufficient to support utilization management program activities, to generate management reports to enable it to effectively monitor and manage health care services provided to its members, and sufficient to meet the filing requirements of this rule.
- (J) Each managed care organization shall coordinate the utilization management program with its other medical management activities, including quality management, credentialing verification, provider contracting, data reporting, grievance procedures, processes for assessing member satisfaction, and risk management.
- (K) Each managed care organization shall provide members and providers with access to its review staff by a toll-free number or such other secure mechanism with the goal of facilitating transmission of the information necessary for utilization review during a single, initial contact. Evidence that managed care organization reviewers are not promptly available when a provider or member initiates or schedules a required utilization review contact, that members or providers are required to initiate repeated telephone calls or voice mail transfers or are being required to submit duplicates of or

redundant documentation, or similar evidence of repeated failure to facilitate reasonable utilization review practices may be considered a violation of this rule.

- (L) When conducting utilization review, the managed care organization shall collect only the information necessary to certify the admission, procedure or treatment, length of stay, frequency and duration of services, including, for mental health and substance abuse services, information on the factors described in Section 3.1(E)6 of this rule.
- (M) Compensation to persons providing utilization review services for a managed care organization shall not contain incentives, direct or indirect, for those persons to limit access to medically necessary care. Compensation to such persons may not be based, directly or indirectly, on the quantity or type of adverse determinations rendered.

3.2 Utilization Review Procedures.

- (A) Each managed care organization shall maintain written procedures for making utilization review decisions and for notifying members, representatives of members, and providers acting on behalf of members of its decisions consistent with the requirements of this rule. For purposes of this Part, the term "member" shall include an authorized representative of the member.
- (B) For purposes of this section, the following reviews shall be treated as urgent:
 - 1. all pre-service requests related to mental health and substance abuse conditions, unless the member or treating provider informs the managed care organization that the request is not urgent;
 - 2. all pre-service pharmacy benefit determinations, unless the member or treating provider informs the managed care organization that the request is not urgent;
 - 3. all pre-service requests related to whether use of a prescription drug for the treatment of cancer is medically necessary or is an experimental or investigational use; and
 - 4. all requests designated as urgent by a member's health care provider or by the member.
- (C) Concurrent Review - Timeframe for Completion and Notification:
 - 1. If an ongoing course of treatment has been approved, a decision by a managed care organization to deny, limit, reduce, modify or terminate coverage or payment for such course of treatment, or to deny a request by or on behalf of a member to extend the course of treatment, in whole or in part, shall constitute an adverse benefit determination.

2. A request to continue or extend a facility stay or other ongoing course of treatment as described in subsection 3.1(G)3. of this Rule shall be decided as soon as possible consistent with the medical exigencies of the case. A managed care organization shall notify the member and treating provider (if known) in accordance with paragraph (G) of this section of the managed care organization's benefit determination (whether adverse or not) as soon as possible consistent with the medical exigencies of the case, but not later than twenty-four (24) hours after receipt of the request.
3. In the case of an adverse concurrent review benefit determination regarding a facility stay or other ongoing course of treatment as described in subsection 3.1(G)3. of this Rule, when the grievance is requested and conducted consistent with the requirements of Section 3.1(G)3 of this Rule, neither the member nor the provider shall be liable for any services provided before notification to the member of the adverse benefit determination and the final outcome of any grievance or independent external review, unless the treating provider or designee has refused or repeatedly failed to engage in communication with the managed care organization when it has been offered at a time in a manner reasonably convenient for the provider, in which case the provider and not the member shall be liable for any services provided.
4. The managed care organization shall notify the treating provider and member of the determination orally as soon as the determination has been made. Written (either hard copy, or, if elected by the member or treating provider, appropriately secure electronic) confirmation of the determination shall be sent to the treating provider and the member within twenty-four (24) hours of the oral notification.

(D) Urgent, Pre-Service Review - Timeframe for Completion and Notification:

1. For urgent pre-service review determinations, a managed care organization shall notify the member and treating provider (if known) in accordance with paragraph (G) of this section of the managed care organization's benefit determination (whether adverse or not) as soon as possible consistent with the medical exigencies of the case, but not later than seventy-two (72) hours after receipt of the request.
2. This period may be extended by not less than forty-eight (48) hours by the managed care organization if such extension is necessary due to a failure of the member or provider to submit the information necessary to decide the request. Oral and written notification of the need for additional information shall be provided to the member and the treating provider (if known) as soon as possible, but not later than twenty-four (24) hours after receipt of the request.
3. The managed care organization shall notify the treating provider (if known) and member of the determination orally as soon as the determination has been made. Written (either hard copy, or if elected by the member or treating provider,

appropriately secure electronic) confirmation of the determination shall be sent to the treating provider (if known) and the member within twenty-four (24) hours of the oral notification.

(E) Non-Urgent, Pre-Service Review - Timeframe for Completion and Notification:

1. For non-urgent, pre-service review determinations, a managed care organization shall notify the member and treating provider (if known) in accordance with paragraph (G) of this section of the managed care organization's benefit determination (whether adverse or not) as soon as possible consistent with the medical exigencies of the case, but not later than fifteen (15) calendar days after receipt of the request. Written (either hard copy or, if elected by the member or treating provider, appropriately secure electronic) confirmation of the determination shall be sent to the treating provider (if known) and the member.
2. This period may be extended one time by the managed care organization for up to fifteen (15) calendar days, provided that the managed care organization both determines that such an extension is necessary due to matters beyond its control and notifies the treating provider (if known) and member prior to the expiration of the initial fifteen (15) calendar day period, of the circumstances requiring the extension of time and the date by which the managed care organization expects to render a decision. If such an extension is necessary due to a failure of the member or treating provider to submit the information necessary to decide the request, the notice of extension shall specifically describe the required information, and the member or treating provider shall be afforded at least forty-five (45) calendar days from receipt of the notice within which to provide the specified information.

(F) Post-Service Review - Timeframe for Completion and Notification:

1. For post-service review determinations, a managed care organization shall notify the member and treating provider (if known), in accordance with paragraph (G) of this section, of the managed care organization's benefit determination (whether adverse or not) within a reasonable period of time, but not later than thirty (30) calendar days after receipt of the request. Written (either hard copy or, if elected by the member or treating provider, appropriately secure electronic) confirmation of the benefit determination shall be sent to the treating provider (if known) and the member.
2. This period may be extended one time by the managed care organization for up to fifteen (15) calendar days, provided that the managed care organization both determines that such an extension is necessary due to matters beyond its control and notifies the member and treating provider (if known), prior to the expiration of the initial thirty (30) calendar day period, of the circumstances requiring the extension of time and the date by which the managed care organization expects to render a decision. If such an extension is necessary due to a failure of the

member or treating provider to submit the information necessary to decide the request, the notice of extension shall specifically describe the required information, and the member or treating provider shall be afforded at least forty-five (45) calendar days from receipt of the notice within which to provide the specified information.

(G) Contents of Notice of Benefit Determination: A written or electronic notification of a benefit determination shall set forth the following information in a manner calculated to be understood by the member:

1. a statement of the reviewer's understanding of the request;
2. if applicable, a description of any additional material or information necessary for the member to perfect the request and an explanation of why such material or information is necessary;
3. if the review resulted in authorization, a clear and complete description of the service(s) that were authorized and all applicable limitations or conditions;
4. if the review resulted in an adverse benefit determination, in whole or in part:
 - a. the specific reason or reasons for the adverse benefit determination;
 - b. the text of the specific health benefit plan provisions on which the determination is based;
 - c. if the adverse benefit determination is based on medical necessity, an experimental/investigational exclusion, is otherwise an appealable decision pursuant to Vermont's independent external review laws, or is otherwise a medically-based determination, an explanation of the scientific or clinical judgment for the determination, and an explanation of how the clinical review criteria and the terms of the health benefit plan apply to the member's medical circumstances;
 - d. if an internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse benefit determination, either the specific rule, guideline, protocol, or other similar criterion; or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse benefit determination and that a copy of such rule, guideline, protocol, or other criterion will be provided to the member upon request and free of charge within two (2) business days or, in the case of a concurrent or urgent pre-service review, immediately upon request;

- e. if the review is a concurrent or pre-service review, what, if any, alternative covered benefit(s) the managed care organization would consider to be medically necessary and would authorize if requested;
- f. a description of the managed care organization's grievance procedures and the time limits applicable to such procedures;
- g. in the case of a concurrent review determination or an urgent, pre-service request, a description of the expedited grievance review process that may be applicable to such requests;
- h. a description of the requirements and timeframes for filing grievances and/or a request for independent external review in order for the member or provider to be held harmless pending the outcome, where applicable;
- i. notice of the right to request independent external review after a grievance determination, in the language, format and manner prescribed by the Department; and
- j. local and toll-free numbers for the Department's health care consumer assistance section and the Vermont Office of Health Care Ombudsman.

3.3 Grievance Procedures.

- (A) Each managed care organization shall establish and maintain a grievance review process that provides a member with a reasonable opportunity for a full and fair review of the grievance, for members who are dissatisfied with the availability, delivery or quality of their health care services, including adverse benefit determinations, claims payments, the handling of or reimbursement for such services, or any other matter pertaining to their contractual relationship with the managed care organization.
- (B) For purposes of this section, the following grievances shall be treated as urgent:
 - 1. all pre-service grievances related to mental health and substance abuse conditions that were handled as urgent at the review level, unless:
 - a. the member has authorization for the treatment in dispute such that treatment can continue uninterrupted for the duration of any non-expedited grievance(s) and independent external review, if any;
 - b. the request is for a service scheduled sufficiently in the future such that non-expedited grievance(s) and independent external review, if any, can be completed prior to the date scheduled for the service; or

- c. the managed care organization otherwise has good cause to believe that it is not medically necessary to expedite the timeframe for grievance review, and the member and provider agree;
 - 2. all pre-service pharmacy benefit grievances, unless:
 - a. the member has a sufficient supply of the medication in dispute to ensure that treatment can continue uninterrupted for the duration of any non-expedited grievance(s) and independent external review, if any; or
 - b. the managed care organization otherwise has good cause to believe that it is not medically necessary to expedite the timeframe for grievance review, and the member and provider agree;
 - 3. all pre-service requests related to whether use of a prescription drug for the treatment of cancer is medically necessary or is an experimental or investigational use; and
 - 4. any grievance designated as urgent by a member's health care provider or by the member.
- (C) Managed care organizations shall provide no more than two (2) levels of grievance, the second level of which shall be voluntary to the member. With respect to the voluntary second level grievance, the managed care organization shall:
- 1. waive any right to assert that a member has failed to exhaust administrative remedies because the member did not elect to pursue the voluntary second level grievance;
 - 2. agree that any statute of limitations or other defense based on timeliness is tolled during the time that a voluntary second level grievance is pending;
 - 3. require that members who choose to elect the voluntary second level grievance may do so only after exhaustion of the required first level grievance process;
 - 4. provide sufficient information regarding the voluntary second level grievance process to enable the member to make an informed judgment about whether to pursue the voluntary second level grievance, including:
 - a. a statement that the decision of a member as to whether or not to pursue the voluntary second level grievance will have no effect on the member's rights to any other benefits; and
 - b. information about the applicable rules, the member's right to representation, the process for selecting the decision maker, and the

circumstances, if any, that may affect the impartiality of the decision maker.

5. not impose any fees or costs on a member or provider who elects to pursue a voluntary second level grievance;
 6. include the right of the member to meet with one (1) or more of the reviewers, at the member's request, before a final determination is made on the voluntary second level grievance. The managed care organization shall provide for either an in-person meeting or a telephone meeting; however, if it is inconvenient for the member to participate in the manner offered by the managed care organization, the other method of meeting must be made available to the member. The member's treating provider(s) and any other person(s) requested by the member is (are) entitled but not required to participate in such a meeting or call. The meeting date shall be arranged in consultation with the member. The managed care organization shall not unreasonably deny a request for postponement of the review made by a member. The right to have a voluntary second level grievance considered shall not be made conditional on a member's appearance either in person or by telephone at such a meeting.
- (D) The grievance process of a managed care organization will not be deemed to provide a member with a reasonable opportunity for a full and fair review of a grievance unless the grievance process:
1. provides members at least one hundred eighty (180) calendar days following receipt of a notification of an adverse benefit determination within which to request a first level grievance and at least ninety (90) calendar days following receipt of notification of an adverse determination on a first level grievance within which to request a voluntary second level grievance;
 2. provides members the opportunity to submit written comments, documents, records, and other information relating to the grievance;
 3. provides that a member shall be provided reasonable access to, and copies of, all documents, records, and other information relevant to the member's grievance upon request and free of charge within two (2) business days or, in the case of a concurrent or urgent pre-service review, immediately upon request. Whether a document, record, or other information is relevant to a grievance shall be determined by reference to the definition of "relevant document, record or other information" in this rule;
 4. provides for a review that takes into account all comments, documents, records, and other information submitted by the member relating to the grievance, without regard to whether such information was submitted or considered in the initial benefit determination or during the first level grievance, in the case of a voluntary second level grievance;

5. provides for a review that does not afford deference to the initial adverse benefit determination or the adverse determination on first level grievance, in the case of a voluntary second level grievance;
6. ensures that the person or persons reviewing a first level grievance on behalf of the managed care organization shall not have been involved with the adverse benefit determination or other issue that is the subject of the grievance, nor shall such person or persons be the subordinate(s) of any individual who was involved with the initial determination or other issue that is the subject of the grievance;
7. ensures that the person or persons reviewing a voluntary second level grievance on behalf of the managed care organization shall not have been involved with the adverse benefit determination or other issue that is the subject of the grievance, or the adverse determination in the first level grievance; nor shall such person or persons be the subordinate(s) of any individual who was involved with the initial determination or other issue that is the subject of the grievance or the first level grievance;
8. provides that, in deciding a first level grievance of an adverse benefit determination that is based in whole or in part on a medical judgment, including determinations with regard to whether a particular treatment, drug, or other item is experimental, investigational, or not medically necessary or appropriate, or based in whole or in part on any other adverse benefit determination that is an appealable decision pursuant to Vermont's independent external review laws, the reviewers shall include at least one (1) clinical peer of the member's treating provider as defined in this Rule. The managed care organization's medical director or the medical director's designee shall offer to, and if the offer is accepted, shall directly communicate with the member's treating provider or the treating provider's designee before a resolution of the grievance is made;
9. provides for the identification of any clinical expert(s) whose advice was obtained on behalf of the managed care organization in connection with a member's adverse benefit determination without regard to whether the advice was relied upon in making the determination;
10. provides that any clinical expert(s) engaged for purposes of a consultation related to a grievance shall be an individual who is neither an individual who was consulted in connection with the adverse benefit determination that is the subject of the grievance, or in connection with the first level grievance if the managed care organization elects to engage any clinical expert(s) for a voluntary second level grievance, nor the subordinate of any such individual;
11. in the case of a grievance involving concurrent review or a pre-service grievance involving urgent care, provides for a review process consistent with the time frames required by this rule and permits a request for a concurrent or expedited first or voluntary second level grievance of an adverse benefit determination to

be submitted orally or in writing by the member. All necessary information needed by or to be communicated by the managed care organization, including the managed care organization's benefit determination upon review, shall be accepted by the managed care organization and transmitted between it and the treating provider (if known) and/or the member in the most expeditious form and manner available.

12. provides members who have a disability reasonable accommodations for filing grievances and for participating in the grievance process;
 13. ensures that the managed care organization waives any right to assert that a member has failed to exhaust administrative remedies because the member did not elect to submit a grievance to the voluntary second level of grievance;
 14. provides members for whom English is not a primary language with information in their primary language, if requested, about how to file a grievance and how to participate in the grievance process; and
 15. ensures that persons who are unable to file written grievances may notify the managed care organization of a grievance orally or through another alternative mechanism. The managed care organization shall be responsible for documenting such grievances and providing copies to the members for their use, or the use of the members' representatives.
- (E) For any grievances relating to an adverse benefit determination, a managed care organization shall promptly authorize and/or otherwise arrange for coverage for any covered service that had been denied or restricted and as to which a reversal has been made by its reviewers under this section.
- (F) First-Level Concurrent Review Grievance - Timeframe for Completion and Notification:
1. A grievance related to a request to continue or extend a course of treatment shall be decided as soon as possible consistent with the medical exigencies of the case. A managed care organization shall notify the member and treating provider (if known) in accordance with paragraph (P) of this section of the managed care organization's determination (whether adverse or not) as soon as possible consistent with the medical exigencies of the case, but not later than twenty-four (24) hours after receipt of the grievance.
 2. Consistent with the requirements of Section 3.1(G)3 of this Rule, in the case of a grievance related to an adverse concurrent review determination, neither the member nor the provider shall be liable for any services provided before notification to the member of the adverse benefit determination and the final outcome of any grievance or independent external review, unless the treating provider or designee has refused or repeatedly failed to engage in communication with the managed care organization when it has been offered at a time in a

manner reasonably convenient for the provider, in which case the provider and not the member shall be liable for any services provided.

3. The managed care organization shall notify the treating provider and member of the determination orally as soon as the determination has been made. Written (either hard copy or, if elected by the member or treating provider, appropriately secure electronic) confirmation of the determination shall be sent to the treating provider and member within twenty-four (24) hours of the oral notification.

(G) First-Level Urgent, Pre-Service Grievance - Timeframe for Completion and Notification:

1. In the case of a grievance relating to an urgent, pre-service request, the managed care organization shall notify the member and the member's treating provider (if known) in accordance with paragraph (P) of this section of the managed care organization's determination (whether adverse or not) as expeditiously as the member's medical condition requires, but not later than seventy-two (72) hours after receipt of the grievance.
2. The managed care organization shall notify the treating provider (if known) and member of the determination orally as soon as the determination has been made. Written (either hard copy, or if elected by the member or treating provider, appropriately secure electronic) confirmation of the determination shall be sent to the treating provider (if known) and the member within twenty-four (24) hours of the oral notification.

(H) First-Level Non-Urgent, Pre-Service Grievance - Timeframe for Completion and Notification:

1. In the case of a grievance relating to a non-urgent, pre-service request, the managed care organization shall notify the member and the member's treating provider (if known) in accordance with paragraph (P) of this section of the managed care organization's determination (whether adverse or not) as expeditiously as the member's medical condition requires, but not later than thirty (30) calendar days after receipt of the grievance.
2. Written (either hard copy or, if elected by the member or treating provider, appropriately secure electronic) confirmation of the determination shall be sent to the treating provider (if known) and the member.

(I) First-Level Post-Service Grievance - Timeframe for Completion and Notification:

1. In the case of a post-service grievance, the managed care organization shall decide and notify the member and the member's treating provider (if known) in accordance with paragraph (P) of this section of the managed care organization's determination (whether adverse or not) within a reasonable period of time but not later than sixty (60) calendar days after receipt of the grievance.

2. Written (either hard copy or, if elected by the member or treating provider, appropriately secure electronic) confirmation of the determination shall be sent to the treating provider (if known) and the member.

(J) First-Level Grievance Unrelated to an Adverse Benefit Determination - Timeframe for Completion and Notification:

1. For grievances not related to adverse benefit determinations, members shall be notified within sixty 60 calendar days after receipt of the grievance.
2. Written (either hard copy or, if elected by the member, appropriately secure electronic) confirmation of the determination shall be sent to the member.

(K) Voluntary Second-Level Concurrent Review Grievance - Timeframe for Completion and Notification:

1. A grievance related to a request to continue or extend a course of treatment shall be decided as soon as possible consistent with the medical exigencies of the case. A managed care organization shall notify the member and treating provider (if known) in accordance with paragraph (P) of this section of the managed care organization's determination (whether adverse or not) as soon as possible consistent with the medical exigencies of the case, but not later than twenty-four (24) hours after receipt of the grievance.
2. Consistent with the requirements of Section 3.1(G)3 of this Rule, in the case of a grievance related to an adverse concurrent review determination, neither the member nor the provider shall be liable for any services provided before notification to the member of the adverse benefit determination and the final outcome of any grievance or independent external review, unless the treating provider or designee has refused or repeatedly failed to engage in communication with the managed care organization when it has been offered at a time in a manner reasonably convenient for the provider, in which case the provider and not the member shall be liable for any services provided.
3. The managed care organization shall notify the treating provider and member of the determination orally as soon as the determination has been made. Written (either hard copy or, if elected by the member or treating provider, appropriately secure electronic) confirmation of the determination shall be sent to the treating provider and the member within twenty (24) hours of the oral notification.

(L) Voluntary Second-Level Urgent, Pre-Service Grievance - Timeframe for Completion and Notification:

1. In the case of a voluntary second-level grievance relating to an urgent, pre-service request, the managed care organization shall notify the member and the member's treating provider (if known) in accordance with paragraph (P) of this

section of the managed care organization's determination (whether adverse or not) as expeditiously as the member's medical condition requires, but not later than seventy-two (72) hours after receipt of the voluntary second-level grievance.

2. The managed care organization shall notify the treating provider (if known) and member of the determination orally as soon as the determination has been made. Written (either hard copy, or, if elected by the member or treating provider, appropriately secure electronic) confirmation of the determination shall be sent to the treating provider and the member within twenty-four (24) hours of the oral notification.

(M) Voluntary Second-Level Non-Urgent, Pre-Service Grievance - Timeframe for Completion and Notification:

1. In the case of a voluntary second-level grievance relating to a non-urgent, pre-service request, the managed care organization shall notify the member and the member's treating provider (if known) in accordance with paragraph (P) of this section of the managed care organization's determination (whether adverse or not) as expeditiously as the member's medical condition requires, but not later than thirty (30) calendar days after receipt of the grievance.
2. Written (either hard copy or, if elected by the member or treating provider, appropriately secure electronic) confirmation of the determination shall be sent to the treating provider (if known) and the member.

(N) Voluntary Second-Level Post-Service Grievance - Timeframe for Completion and Notification:

1. In the case of a voluntary second-level post-service grievance, the managed care organization shall notify the member and the member's treating provider (if known) in accordance with paragraph (P) of this section of the managed care organization's determination (whether adverse or not) within a reasonable period of time but not later than sixty (60) calendar days after receipt of the grievance.
2. Written (either hard copy or, if elected by the member or treating provider, appropriately secure electronic) confirmation of the determination shall be sent to the treating provider (if known) and the member.

(O) Voluntary Second-Level Grievance Unrelated to an Adverse Benefit Determination - Timeframe for Completion and Notification:

1. For voluntary second-level grievances not related to adverse benefit determinations, members shall be notified within sixty (60) calendar days after receipt of the grievance.

2. Written (either hard copy or, if elected by the member, appropriately secure electronic) confirmation of the determination shall be sent to the member.

(P) Contents of Notice of Determination on Grievance: A written or electronic notification of a determination of a grievance shall set forth the following information in a manner calculated to be understood by the member:

1. if the grievance resulted in authorization, a clear and complete description of the service(s) that were authorized and all applicable limitations or conditions;
2. unless the previous adverse benefit determination has been completely overturned:
 - a. the titles and qualifying credentials of the person or persons reviewing the grievance on behalf of the managed care organization;
 - b. a statement of the reviewers' understanding of the member's grievance;
 - c. the specific reason or reasons for the adverse determination;
 - d. the text of the specific health benefit plan provisions on which the determination is based;
 - e. if the adverse benefit determination is based on medical necessity, an experimental/investigational exclusion, is otherwise an appealable decision pursuant to Vermont's independent external review laws, or is otherwise a medically-based determination, an explanation of the scientific or clinical judgment for the determination, and an explanation of how the clinical review criteria and the terms of the health benefit plan apply to the member's medical circumstances;
 - f. if the grievance is concurrent or pre-service, what, if any, alternative covered benefits the managed care organization considers to be medically necessary and would authorize if requested;
 - g. a statement that the member is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the member's grievance within two (2) business days or, in the case of a concurrent or urgent pre-service grievance, immediately upon request. Whether a document, record, or other information is relevant to a grievance shall be determined by reference to the definition of "relevant document, record or other information" in this rule;
 - h. if an internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse benefit determination, either the

specific rule, guideline, protocol, or other similar criterion; or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse benefit determination and that a copy of such rule, guideline, protocol, or other criterion will be provided to the member upon request and free of charge within two (2) business days or, in the case of a concurrent or urgent pre-service review, immediately upon request;

- i. notice of the right to obtain independent external review, in the language, format and manner prescribed by the Department;
- j. the local and toll-free numbers for the Department's health care consumer assistance section and the Vermont Office of Health Care Ombudsman;
- k. in the notice of decision after a first level grievance, a statement describing the voluntary second level of grievance that is available to the member, with sufficient information to enable the member to make an informed judgment about whether to pursue the voluntary second level grievance, including:
 - i. a statement that the decision of a member as to whether or not to pursue the voluntary second level grievance will have no effect on the member's rights to any other benefits or to pursue independent external review;
 - ii. a description of the requirements and timeframes for filing the voluntary second level grievance and/or a request for independent external review in order for the member or provider to be held harmless pending the outcome;
 - iii. information regarding the voluntary second level grievance, including the applicable rules, the member's right to representation, the process for selecting the decision maker, and the circumstances, if any, that may affect the impartiality of the decision maker;
 - iv. a statement that there are no fees or costs for a member or provider who elects to pursue a voluntary second level grievance;
 - v. the time limits applicable to the voluntary second level grievance.

(Q) A managed care organization plan shall maintain written or electronic records documenting all grievances (the grievance register) received during a calendar year. The

managed care plan shall retain the grievance register compiled for a calendar year for at least three (3) years. Each grievance register shall contain, at a minimum, the following information:

1. The identity of the member who filed the grievance, using a unique identification code assigned consistently to that member;
2. A general description of the reason for the grievance;
3. The date the grievance was received by the managed care organization;
4. The date of each review and hearing (if any);
5. Whether the grievance was resolved through the first level of review, or whether it was subject to a second level grievance or independent external review;
6. Whether, and if so when, the managed care organization or member requested an extension, and documentation that the member agreed to the extension;
7. Whether additional information was requested, and the date the information necessary to resolve the grievance was received if an extension was requested; and
8. The resolution of the grievance along with the date it was resolved.

PART 4: ADDITIONAL REQUIREMENTS IF PHARMACEUTICAL BENEFIT MANAGEMENT MECHANISMS ARE USED

4.1 **Required Disclosures Specific to Pharmaceutical Benefits.** In addition to providing the information required by Section 2.2 (A)3r of this rule, a managed care organization and any responsible delegate shall ensure that the primary source of information for members and providers regarding drugs subject to a pharmaceutical benefit management program (PBMP) includes a description of or reference to:

- (A) where applicable, the particular clinical indications for which the PBMP applies (or does not apply) for use of a drug that has multiple indications for use;
- (B) the nature of the clinical information required; by whom, how and where the information must be submitted; how to confirm receipt; and contact information for customer service as well as telephone, fax and other contact information for the reviewing entity(ies), in order to request:
 1. prior authorization;
 2. exceptions from PBMP criteria; and

3. a grievance related to a PBMP.

4.2 Procedures Regarding Changes To Pharmaceutical Benefits.

(A) Whenever a change is made in a PBMP that applies a new or revised dose restriction that causes a prescription for a particular drug not to be covered for the number of doses prescribed, or applies a new or revised substitution, step therapy, prior authorization or any other requirement that causes a particular drug not to be covered until the requirements of that PBMP have been met, the managed care organization and any responsible delegate shall ensure:

1. the change is published in the primary source of PBMP information for members and providers as long in advance as possible but no less than ninety (90) days prior to the effective date of the change;
2. each member who is known to have an active prescription for the drug is individually notified in writing at least ninety (90) days prior to the effective date of the change; and,
3. that if a member requests a fill or refill of a prescription written prior to publication of the change or receipt of the notice required by Subsection (A)1 or (2) of this section; the prescription remains valid; and it is not possible to timely obtain a prescription consistent with the changed requirement, coverage will be provided for an interim supply of the drug and, if relevant, any additional supply that is medically necessary to safely discontinue the drug for up to ninety (90) days or until the prescribing provider can order a new prescription; or, if necessary, until the grievance and independent review process can be initiated and completed. A managed care organization shall not be required to cover an interim supply if:
 - a. member's prescribing provider explicitly consents to the change; or
 - b. the drug has been determined to be unsafe for the treatment of the member's disease or medical condition, has been discontinued from coverage for safety reasons or cannot be supplied by or has been withdrawn from the market by the drug's manufacturer.

4.3 Utilization Management and Grievance Programs and Procedures Specific to Pharmaceutical Benefits.

(A) A managed care organization and any responsible delegate shall review relevant clinical evidence, consult with individual(s) with relevant expertise in pharmacology and/or pharmacy and with health care providers in the same or similar specialties that typically provide and manage the drug regimens subject to the PBMP and proactively assess, on an ongoing basis:

1. the appropriateness of its selection of particular PBMP procedures for particular drugs in particular medical situations;
 2. whether the PBMP procedures it has applied to particular drugs may create a risk of unintended detrimental clinical outcomes in particular medical situations; and
 3. whether complaints, appeals or other feedback from members and providers indicate a need to improve the usability or reduce the burden of its PBMP procedures.
- (B) A managed care organization shall grant an exception to a PBMP requirement and shall provide coverage on the same terms as it would have for the PBMP requirement if the member's prescribing health care provider certifies, based on relevant clinical information about the particular member and sound medical or scientific evidence or the known characteristics of the drug, that the PBMP requirement:
1. has been ineffective or is reasonably expected to be ineffective or significantly less effective in treating this member's condition such that an exception is medically necessary; or
 2. has caused or is reasonably expected to cause adverse or harmful reactions in this member.
- (C) A managed care organization may require a prescribing provider to submit the request for an exception and supporting certification in writing in advance in non-emergency situations if the format and process for submitting written certification facilitates the transmission of necessary information without creating barriers to timely treatment or requiring additional steps or a greater investment of time by the provider in fulfilling other requirements for utilization management, except that:
1. A managed care organization shall accept the advance certification telephonically in a situation designated by the prescribing provider to be an emergency but may require that it later be confirmed in writing.
 2. A managed care organization may accept but shall not require submission of actual medical records that duplicate information provided in the certification unless there is a reason to suspect that that the information in the certification is inaccurate.
- (D) In addition to the requirements of Sections 2.2, 3.2 and 3.3 of this rule, plan documents and notices of an adverse benefit determination related to a prescribed drug shall include a detailed explanation of:
1. the information required to be submitted to comply with PBMP requirements for requesting exceptions from PBMP criteria and, if necessary, to file a grievance related to a PBMP;

2. by whom the request and clinical or other required information is to be submitted;
3. how and where information must be submitted, including telephone, fax and other contact information for the reviewing entity(ies);
4. under what circumstances and how an interim supply of medication may be obtained; and
5. the fact that a denial of a request for a PBMP exception is a determination subject to independent external review under Vermont law, and shall include any applicable notice required by the Department and a reference to descriptions of the independent external review process in relevant plan documents.

(E) As long as a drug continues to be prescribed for a member and is considered safe for the treatment of the member's condition, a member who has previously been prescribed an otherwise covered drug that is the subject of PBMP prior authorization, other review and/or denial shall be entitled to coverage for a supply of the drug sufficient to continue treatment through the following time periods, as well as any additional supply that is medically necessary to safely discontinue the drug if the denial is ultimately upheld:

1. until the PBMP has completed the prior authorization or other review process;
2. if applicable, until all requested internal expedited grievances have been exhausted; and
3. until the independent external review decision is issued, if expedited independent external review is requested within twenty-four (24) hours of the receipt of the final grievance decision and notice of appeal rights by the member, and expedited independent external review is conducted in accordance with the time frames specified by law.

(F) Whenever an exception has been made or a denial of coverage for a prescription drug is overturned as a result of a grievance or independent external review, the managed care organization shall not require utilization review for a refill or a new prescription to continue using the same drug as long as:

1. the member's prescribing provider continues or reinstates treatment with the same drug regimen to treat the same condition of the member in the same or similar circumstances and there has been no significant change in the medical or scientific evidence supporting the exception or overturn of the denial; and
2. the drug continues to be considered safe and effective for treating the member's condition.

- (G) A managed care organization shall not establish a higher tier or increase a drug's tier, co-payment or other cost-sharing requirement solely because a drug was approved for coverage following a grievance or independent external review.
- (H) Nothing in this Part shall be construed to prohibit dispensing of prescriptions consistent with applicable law regarding generic substitution.

PART 5: ADDITIONAL REQUIREMENTS IF THERE ARE ANY RESTRICTIONS OR INCENTIVES PERTAINING TO MEMBER USE OF CONTRACTED OR CERTAIN OTHER PROVIDERS

5.1 Adequacy of Access to Providers and Continuity of Services.

Each managed care organization, either directly or through its provider contracts, shall ensure that covered health care services are accessible to members on a timely basis, as follows. Each managed care organization shall contract with sufficient numbers and types of providers to ensure that all covered health care services for which there are restrictions or incentives for members to use contracted or certain other providers will be provided without unreasonable delay. This requirement must be met in all service areas where the managed care organization has members.

- (A) Travel time standards. Travel times for members of a managed care organization to contracted providers, under normal conditions from their residence or place of business, generally should not exceed the following:
 1. Thirty (30) minutes to a primary care provider;
 2. Thirty (30) minutes to routine, office-based mental health and substance abuse services;
 3. Sixty (60) minutes for outpatient physician specialty care; intensive outpatient, partial hospital, residential or inpatient mental health and substance abuse services; laboratory; pharmacy; general optometry; inpatient; imaging; and inpatient medical rehabilitation services;
 4. Ninety (90) minutes for kidney transplantation; major trauma treatment; neonatal intensive care; and tertiary-level cardiac services, including procedures such as cardiac catheterization and cardiac surgery; and
 5. Reasonable accessibility for other specialty services, including major burn care, organ transplantation (other than kidneys), and specialty pediatric care. This section shall not be construed as restricting or prohibiting a managed care plan from offering such services at so-called "centers of excellence" inside or outside of the service area, as long as the selection of a center of excellence is based on objective quality of care indicators and as long as the benefits are such that it does not create foreseeable medical, practical or financial impediments for the member to be able to timely obtain access to related immediate, episodic and/or ongoing care.

(B) Waiting time standards. Waiting times should generally not exceed the following:

1. Immediate access to emergency care for conditions that meet the definition of "emergency medical condition" set forth in this rule, subject to the provisions of Section 2.4 of this rule;
2. Twenty-four (24) hours or a time frame consistent with the medical exigencies of the case for urgent care (for the purposes of this subsection, outpatient mental health and substance abuse care designated by the member or provider as non-urgent is not considered to be urgent care);
3. Two (2) weeks for non-emergency, non-urgent care;
4. Ninety (90) days for preventive care (including routine physical examinations); and
5. Thirty (30) days for routine laboratory, imaging, general optometry, and all other routine services.

(C) Each managed care organization shall develop and implement written standards or guidelines that address the assessment of contracted provider capacity to provide timely access to health care services.

(D) Each managed care organization shall, either directly or through contracts or other arrangements, provide the services of primary care providers sufficient to respond to initial and basic care needs of members.

(E) Each managed care organization shall permit its members to make at least two (2) visits per calendar year to a contracted gynecological health care provider for reproductive or gynecological care, as well as visits relating to follow-up care for problems identified during such visits, without a referral from the members' primary care providers. All such visits shall be subject to the utilization review procedures used by the managed care organization in accordance with Section 3.2 of this rule.

(F) Each managed care organization shall permit certain new members to continue to use their previous providers, so long as those providers agree to abide by the health benefit plan's payment rates, quality-of-care standards and protocols, and to provide the necessary clinical information to the managed care organization, as follows:

1. New members with life-threatening, disabling or degenerative conditions shall be allowed to continue to see their providers for sixty (60) days from the date of enrollment or until accepted by a contracted provider, whichever is shorter; and
2. Women in their second or third trimester of pregnancy shall be allowed to continue to obtain care from their previous provider until the completion of postpartum care.

- (G) The managed care organization shall establish policies and procedures to ensure the orderly transfer of those members whose providers' contracts with the health benefit plan have expired or been terminated, with or without cause, to other contracted providers. In so doing, each managed care organization shall permit certain members receiving an ongoing course of treatment to continue to use providers whose contracts have been terminated without cause, or whose contracts have not been renewed without cause, so long as those providers agree to abide by the health benefit plan's payment rates, quality-of-care standards and protocols, and to provide the necessary clinical information to the managed care organization, as follows:
1. Members with life-threatening, disabling or degenerative conditions shall be allowed to continue to see their providers for sixty (60) days from the date of termination or non-renewal or until accepted by a contracted provider, whichever is shorter; and
 2. Women in their second or third trimester of pregnancy shall be allowed to continue to obtain care from their previous provider until the completion of postpartum care.
- (H) In the event that a primary care provider referral is needed for access to specialty care, a managed care organization shall establish policies and procedures through which a member with a condition that requires ongoing care from a specialist may obtain a standing referral to a contracted specialist, subject to the utilization review procedures used by the managed care organization in accordance with Section 3.2 of this rule. For purposes of this provision, "standing referral" means a referral for ongoing care to be provided by a contracted specialist that authorizes a series of visits with the specialist for either a specific time period or a limited number of visits, and which is provided according to a treatment plan developed by the member's primary care provider, the specialist, the member and the managed care organization(s). The term "specialist" includes specialists in the treatment of mental health and/or substance abuse conditions and disorders.
- (I) In the event that a primary care provider referral is needed for access to specialty care, a managed care organization shall establish policies and procedures through which a member who has either a life-threatening condition or disease, or a degenerative or disabling condition or disease, that requires specialized health care over a prolonged period of time may receive a referral to a contracted specialist or a contracted specialized facility with expertise in treating the condition or disease, who shall be responsible for and capable of providing and coordinating the member's primary and specialty care. The specialist or specialized facility shall be permitted to treat the member without a referral from the member's primary care provider and may authorize such referrals and health care services as the member's primary care provider would otherwise be permitted to provide or authorize, subject to the utilization review procedures used by the managed care organization in accordance with this rule.

- (J) A managed care organization shall ensure that members may obtain covered services from contracted or non-contracted health care providers within or outside of the service area of the member's health benefit plan when the managed care organization or an independent external review process conducted pursuant to Vermont law determines that the managed care organization does not have a contracted health care provider with appropriate training and experience to provide the services that are medically necessary to meet the particular health care needs of the member, subject to the utilization review procedures used by the health benefit plan in accordance with this rule. In this circumstance:
1. The managed care organization shall assist the member by locating a provider that is contracted, otherwise affiliated or willing to arrange a single case agreement and that has the appropriate training and experience to provide the services that are medically necessary to meet the particular health care needs of the member. Any such provider shall be in a location that is reasonably accessible to the member consistent with the member's medical circumstances if the provider does not meet the travel time standards specified in this rule.
 2. If no provider meeting the specifications described in Subsection (J)1 of this section is available and accessible to the member on a timely basis, the managed care organization shall provide the member with coverage for services from a non-contracted provider. Coverage shall be consistent with the terms and conditions for coverage of services obtained from a contracted provider within the service area.
 3. Coverage required pursuant to this subsection shall be without any additional liability to the member whether the service is provided by a contracted or non-contracted provider. The member shall not be responsible for any additional costs incurred by the managed care organization under this paragraph other than any copayment, coinsurance or deductible applicable to the level of coverage required by this subsection.
- (K) When a member or subscriber temporarily lives, works, attends school or otherwise temporarily resides outside of the service area, requires medically necessary services that would be covered under the health benefit plan if the member were able to access care from contracted providers within the service area, and it is medically necessary that the services be provided promptly, locally and not delayed until the member's return to the service area, the managed care organization shall:
1. Assist the member in locating a provider in the member's location that is contracted, otherwise affiliated or willing to arrange a single case agreement and that has the appropriate training and experience to provide the services that are medically necessary to meet the particular health care needs of the member. Coverage shall be consistent with the terms and conditions of the member's certificate for coverage of services obtained from a contracted provider within the service area. There shall be no additional liability to the member.

2. If no provider that has the appropriate training and experience to provide the services that are medically necessary to meet the particular health care needs of the member in the member's location is contracted, affiliated or willing to arrange a single case agreement, the managed care organization shall:
 - a. provide clear notice to the member that the member may be liable for any balance between the amount paid or reimbursed by the managed care organization and the non-contracted provider's charges, and provide the member with coverage consistent with the terms and conditions in the member's certificate, if the certificate allows for coverage of the service outside of the service area; and
 - b. provide clear notice to the member that the member may be liable for any balance between the amount paid or reimbursed by the managed care organization and the non-contracted provider's charges, and provide the member with coverage consistent with the terms and conditions in the member's certificate for coverage of services within the service area, if the certificate does not ordinarily allow for coverage of the service outside of the service area; and
 - c. pay or reimburse the non-contracted provider for services provided subject to this subsection the reasonable and customary value for the health care services rendered. If the managed care organization has complied with its obligations under this section, it is not required to assume liability if the non-contracted provider seeks additional compensation.

5.2 Credentialing Verification Practices.

- (A) Each managed care organization shall verify the credentials of all contracted health care providers. The managed care organization shall establish procedures to review and evaluate provider credentials both upon application of the health care provider to become employed by or to contract with the managed care organization and at least once every three (3) years thereafter. The initial verification of credentials or provisional credentialing shall be completed before entering into the employment or contractual relationship. Full credentialing shall be completed prior to the managed care organization's listing a health care provider as a contracted provider in any marketing and member materials.
- (B) Each managed care organization shall establish a credentialing verification committee consisting of licensed physicians and other health care providers to review credentialing information and supporting documents and make decisions regarding credentialing verification. The medical director of the managed care organization shall be responsible for, and participate in, health care provider credentialing verification.

- (C) Each managed care organization shall develop and maintain credentialing criteria to be used in evaluating each provider application consistent with the requirements of this rule. These criteria, and the managed care organization's credentialing verification policies and procedures, shall be made available to contracted providers and provider applicants upon written request.
- (D) Except as otherwise provided by law, all information obtained in the credentialing process shall be kept confidential, except that it shall be subject to review and correction of any erroneous information by the health care provider whose credentials are being verified. Records and documents relating to a health care provider's credentialing verification process shall be retained by the managed care organization for at least three years.
- (E) Initial Credentialing: Prior to employing or contracting with a health care provider seeking to become a contracted provider, a managed care organization shall:
1. obtain primary verification of at least the following information regarding individual health care providers, to the extent applicable: current license to practice; professional liability coverage; at least five (5) years' history of professional liability claims that resulted in settlements or judgments paid on behalf of the provider; status of hospital privileges; specialty board or other certification status; current Drug Enforcement Agency (DEA) registration or Controlled Dangerous Substances (CDS) certificate, as applicable; graduation from an accredited school; work history; and completion of post-graduate training;
 2. obtain, through either primary verification or secondary verification from an approved source, to the extent applicable, the health care provider's license history in Vermont and all other states, including dates, times, and places of all applications for license privileges; any action taken on such applications; challenges to licensure or registration; the voluntary or involuntary relinquishment of a license; any state sanctions, restrictions or conditions on licensure or limitations on the scope of practice; Medicare and Medicaid sanctions; and malpractice history;
 3. obtain and review an application and signed attestation from the provider that includes a statement that the application is correct and complete; addresses the provider's ability to perform the essential functions of the position with or without accommodation; indicates a lack of present illegal drug use; and includes any history of loss of license, felony conviction, disciplinary action and any loss/limitation of privileges;
 4. obtain a copy of the insurance policy declaration page from the malpractice carrier to verify current malpractice insurance coverage;

5. with respect to a physician who has completed residency or fellowship requirements within twelve (12) months prior to anticipated employment or contract effective date and who the managed care organization determines is eligible for provisionally credentialed status, obtain primary-source verification of a current, valid license to practice; the application and attestation described in Subsection 5.2(E)3 of this rule; and the past five (5) years of malpractice claims or settlements from the malpractice carrier or the results of a National Practitioner Data Bank or Healthcare Integrity and Protection Data Bank query. The managed care organization shall ensure that no provider remains in provisionally credentialed status for more than sixty (60) days; and
 6. with respect to health care facilities, obtains primary verification that confirms the provider is in good standing with applicable state and/or federal regulatory bodies and, if accredited, with the applicable accrediting entity.
- (F) Recredentialing: At least once every three (3) years after the initial verification of credentials, each managed care organization shall recredential each of its contracted providers in the following manner:
1. Obtain primary verification of current license; current DEA registration or CDS certificate, as applicable; history of professional liability claims that resulted in settlement or judgment paid by or on behalf of the provider; and specialty board certification status, to the extent applicable; and
 2. Obtain and review the items specified in Subsections 5.2(E)3 and 4 of this rule for individual providers; and, for health care facilities, the items specified in Subsection 5.2(E)6.
- (G) Ongoing Monitoring of Credentials: The managed care organization shall implement a process for collecting and reviewing the following information between credentialing cycles, within thirty (30) days of its release or at least every six (6) months, as applicable, and shall have a policy that sets forth guidelines for appropriate intervention or disposition when it identifies instances of poor quality that could affect the health or safety of members:
1. sanctions or limitations on licensure;
 2. Medicare and Medicaid sanctions;
 3. complaints; and
 4. information known to the managed care organization regarding injury that occurred while the member was receiving care from the provider.

- (H) Each managed care organization shall require all health care providers to notify the managed care organization of any changes in the status of any of the items enumerated in this section at any time.
- (I) Nothing in this section shall be construed to require a managed care organization to contract with a provider solely because the provider meets the managed care organization's credentialing verification standards, or to prevent a managed care organization from using separate or additional criteria in selecting the health care providers it employs or with whom it contracts, unless otherwise prohibited by law. However, no managed care organization shall refuse to initially credential, or refuse to re-verify the credentials of, a health care provider solely because the provider treats a substantial number of patients who require expensive or uncompensated care.
- (J) Each managed care organization shall establish an appeal process through which a health care provider denied participation in the managed care organization may obtain review of that decision, as well as a process for the review of a decision by a managed care organization to reduce, suspend, or terminate the privileges of a contracted provider. The managed care organization shall communicate these processes to providers who have been denied participation or continuing participation with the managed care organization. The managed care organization shall document information supporting credentialing and participation decisions in providers' credentialing files.

5.3 Provider Contracting, Fiscal Incentives and Disincentives.

- (A) Each managed care organization shall contract in writing with each contracted health care provider.
- (B) No managed care organization shall include any provision in a contract with a health care provider that prohibits the health care provider from disclosing to members or potential members information about the contract or the members' health benefit plan that may affect their health or any decision regarding health.
- (C) Each managed care organization shall develop selection standards for contracted providers, including primary care providers and specialists, to be used in determining the selection of health care providers with whom the managed care organization contracts, including credentialing verification as required in Section 5.2 of this rule. Selection criteria shall not be established in a manner that would exclude providers because they treat or specialize in treating populations presenting a risk of higher-than-average claims, losses or health services utilization or provide a higher-than-average level of uncompensated care. Copies of the selection standards shall be made available to contracted providers and to the Department on request. This provision shall not be construed to prohibit a managed care organization from declining to select a provider who fails to meet other legitimate selection criteria of the managed care organization, or as requiring the managed care organization to employ specific providers or types of providers who may meet its selection criteria, or as requiring the managed care

organization to contract with or retain more providers or types of providers than are necessary to maintain an adequate network unless otherwise prohibited by law.

- (D) Each managed care organization shall establish an appeal process through which a health care provider denied a contract with the managed care organization, or whose contract is not renewed based on its selection criteria, may obtain review of that decision. The appeal process shall include written notification to the provider of the decision against allowing contracting, or against renewal of a contract, which shall include a statement of the reasons for the managed care organization's decision not to contract or to renew the contract. It shall also include reasonable time limits for taking and resolving the appeals, and a reasonable opportunity for providers to respond to the managed care organization's statement of reasons supporting its decision not to contract or to renew a contract.
- (E) Each managed care organization shall use methods consistent with national standards to maximize the validity of provider-specific performance information and shall establish a procedure that permits health care providers to review their own results on performance measures intended for public reporting in advance of their release. The procedure shall include a reasonable opportunity for a provider to request correction of any inaccuracies prior to publication of the data and reasonable procedures and time limits for resolving any related disputes. If the performance measures are derived from claims data without any medical record review, the managed care organization, if requested by the provider, shall confirm those results with a review of medical records prior to public reporting. The managed care organization shall promptly correct inaccuracies where warranted.
- (F) No managed care organization shall prohibit a contracted provider from, or penalize a contracted provider for, discussing treatment options with members regardless of the managed care organization's position on the treatment options, or advocating on behalf of members within the utilization review or grievance processes established by the managed care organization, nor shall it penalize a provider because the provider in good faith reports to state or federal authorities any act or practice by the managed care organization that jeopardizes patient health or welfare.
- (G) Each provider contract shall contain or incorporate by reference provisions clearly stating the requirements and responsibilities of the managed care organization and contracted providers with respect to administrative policies and programs, including but not limited to payment terms, utilization review, quality improvement programs, chronic care programs, credentialing, grievance procedures, data reporting requirements, confidentiality requirements, and any other applicable provisions required by federal or state law. The contract must allow the provider to participate in the managed care organization's quality management program, dispute resolution process, and utilization management program. The contract shall require contracted providers to notify the managed care organization of any changes that would impact the provider's credentialing status or ongoing availability to members.

- (H) No provider contract shall contain a provision offering an inducement to a provider to forego providing medically necessary services to a member or referring a member to such services.
- (I) Each provider contract shall contain provisions to ensure the availability and confidentiality of the health records necessary to monitor and evaluate the quality of care, and to conduct medical and other health care evaluations and audits to determine, on a concurrent or retrospective basis, the necessity and appropriateness of care provided to members. Each provider contract shall include provisions requiring the provider to make health records available as required by law to appropriate state and federal authorities involved in assessing the quality of care or investigating the grievances or complaints of members, and to comply with the applicable state and federal laws related to the confidentiality of medical or health records.
- (J) Each managed care organization shall establish a mechanism for informing each contracted provider on an ongoing and current basis of the specific covered health services for which the provider will be responsible, including any limitations or conditions on the services.
- (K) Each managed care organization shall inform its primary care providers of their responsibility to provide referrals and any specific procedures that must be followed in providing referrals.
- (L) Every contract between a provider and a managed care organization shall include a "hold harmless" provision specifying protection for the managed care organization's members in a form substantially similar to the following:
- "Provider agrees that in no event, including nonpayment by the managed care organization, insolvency of the managed care organization, or breach of this agreement, shall the provider bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against a member or a person (other than the managed care organization) acting on behalf of the member for services provided pursuant to this agreement. This agreement does not prohibit the provider from collecting coinsurance, deductibles or copayments, as specifically provided in the certificate of coverage, or fees for uncovered services delivered on a fee-for-service basis to members. This agreement does prohibit the provider from requesting payment from a member for any services that have been confirmed by independent external review obtained through the Department of Banking, Insurance, Securities and Health Care Administration pursuant to Vermont law to be medically unnecessary, experimental, investigational or a medically inappropriate off-label use of a drug."
- (M) Every contract between a managed care organization and a provider shall provide that in the event of the managed care organization's insolvency or other cessation of operations, covered services to a member will continue through the period for which a premium has

been paid to the managed care organization on behalf of the member or until the member's discharge from an inpatient facility, whichever period is greater. Covered benefits to a member confined in an inpatient facility on the date of insolvency or other cessation of operations will continue until the member's continued confinement in the facility is no longer medically necessary.

- (N) The contract provisions that satisfy the requirements of paragraphs (L) and (M) of this section shall be construed in favor of the member, shall survive the termination of the contract regardless of the reason for termination, including the insolvency of the managed care organization, and shall supersede any oral or written contrary agreement between a provider and a member or member's representative if the contrary agreement is inconsistent with the "hold harmless" and continuation of covered services provisions required in those paragraphs.
- (O) A managed care organization and its contracted providers shall provide at least sixty (60) days final written notice to each other before terminating a contract without cause. Such notices shall not issue unless and until negotiations have concluded and a final decision on termination has been reached. Within five (5) working days of the date that the provider either gives or receives final notice of termination, either for or without cause, the provider shall supply the managed care organization with a list of his or her patients that are members of the managed care organization.
- (P) After issuance or receipt of the final notice referenced in Subsection 5.3(O), the managed care organization shall provide written notice of the termination of a provider contract to all members who are patients seen on a regular basis by the provider whose contract is terminating. This notice shall be provided at least six (6) weeks prior to the anticipated date of a termination without cause, and shall be provided on or, if possible, before the date the managed care organization or provider terminates the contract for cause. Where a contract termination involves a primary care provider, all members who are patients of that provider shall also be notified. Each managed care organization shall establish procedures for the resolution of administrative, payment or other disputes between providers and the managed care organization.
- (Q) Nothing in this section shall be construed to prohibit a managed care organization from declining to select a provider, or from renewing the contract of a contracted provider, based on that provider's failure to conform to the managed care organization's quality of care standards and quality management program.
- (R) No contract between a managed care organization and a health care provider shall contain any clause purporting to transfer to the provider, other than a medical group, by indemnification or otherwise, any liability relating to activities, actions or omissions of the managed care organization as opposed to those of the provider.

5.4 Quality Management Requirements For Managed Care Organizations Not Subject to Part 6.

- (A) Each managed care organization subject to this Part but not to Part 6 of this rule shall have an internal quality management program that includes at least the following components:
1. A peer review or quality management committee or comparable designated committee responsible for quality management activities;
 2. Accountability of the committee to the board of directors or other governing authority of the organization;
 3. Participation by an appropriate base of providers and support staff;
 4. Supervision by the medical director of the organization;
 5. Regularly scheduled meetings; and
 6. Minutes or records of the meetings, which describe in detail the actions of the committee, including problems discussed, data and other quality management findings, recommendations made, quality improvement activities implemented, the results of those activities and any other pertinent information.

PART 6: ADDITIONAL QUALITY AND CARE MANAGEMENT REQUIREMENTS FOR CERTAIN MANAGED CARE ORGANIZATIONS

6.1 Medical Records Practices.

- (A) Each managed care organization shall adopt written policies and procedures that shall be available to managed care organization staff and providers in hard copy, on the internet, and in a format suitable for electronic mailing, and that address the following:
1. Requirements that clinical records be maintained in a manner that is current, detailed and organized and that permits effective member care and quality review. In instances where managed care organizations do not provide care directly, they shall require their providers to maintain records in the same manner. Records may be written or electronic; and
 2. Minimum content, confidentiality protections, retention, and access by members to their individual records, which shall include the right of a member to see the member's individual medical records upon request during regular business hours and to copy those records for a fee that is consistent with legal requirements. In addition, managed care organizations that provide direct patient care shall

include policies that address the processing and storage of records, disposal procedures, and retrieval and distribution procedures.

- (B) The managed care organization shall have a system to access and audit the content of clinical records of high volume primary care providers at least once every three (3) years, to ensure that they are legible, organized, complete, and demonstrate compliance with any other clinical record-keeping standards established by the managed care organization. Managed care organizations or their delegates that contract with mental health providers shall perform the audit for high volume providers in at least one (1) mental health or substance abuse professional discipline with significant numbers of providers.
- (C) In cases where managed care organizations do not provide direct patient care, clinical records shall be made available to the Department promptly upon request by the Department to the managed care organization, subject to the requirements of this rule.

6.2 Quality Management Program Structure and Administrative Policies and Procedures.

- (A) Managed care organizations shall ensure that health care services provided to their members are informed by generally accepted medical or scientific evidence, and are consistent with prevailing standards of medical practice as recognized by health care professions in the specialties as typically provide the procedure or treatment, or diagnose or manage the medical condition. To that end, managed care organizations shall establish and implement procedures ensuring the availability, accessibility, continuity and quality of care for each member consistent with the member's clinical condition, including procedures for the identification, evaluation, resolution and follow-up of potential and actual problems in the administration and delivery of health care services.
- (B) Each managed care organization shall establish an internal system capable of identifying opportunities to improve care and the managed care organization's management of care. This system shall be structured to identify practices that result in improved health care outcomes, identify problematic utilization patterns, identify those providers that may be responsible for either exemplary or problematic patterns, and foster an environment of continuous quality improvement.
- (C) Each managed care organization shall clearly define the organizational relationships and responsibilities for quality management.
- (D) The medical director of the managed care organization shall have primary responsibility for the quality management activities required of, and carried out by or on behalf of, the managed care organization. The medical director shall approve the written quality management program description and annual quality management work plan, and shall periodically review and revise the program documents and act to ensure their ongoing appropriateness. The medical director shall make verbal and written quality management reports to the managed care organization's governing body at least annually.

- (E) Each managed care organization's quality management program shall include, but not be limited to, the following components:
1. A peer review, quality management or comparable designated committee that is responsible for the managed care organization's quality management activities. The committee shall annually review and approve, or recommend that the board of directors approve, the managed care organization's quality management program description, annual quality improvement goals, and annual quality management work plan. The committee shall also annually review the quality management program evaluation.
 2. Minutes or records of the meetings of the peer review, quality management or other designated committee that describe in detail the committee's actions, including the problems discussed, data and other quality management findings, recommendations made and any other pertinent information. The minutes or records are subject to the confidentiality provisions of 26 V.S.A. § 1443, except that the Department shall have access to them as provided in 18 V.S.A. § 9414(f)(2) and Section 1.6(E) of this rule.
 3. Accountability of the peer review, quality management or other designated committee to the board of directors or other governing authority of the managed care organization. The board shall display appropriate oversight and direction, including monitoring progress on the managed care organization's written quality management work plan and quality improvement goals.
 4. A systematic approach to seeking input from the managed care organization's contracted Vermont providers and incorporating that input into the managed care organization's quality management program. The managed care organization shall, at a minimum, include at least two (2) contracted Vermont providers on the quality management or other designated committee or maintain a committee of at least three (3) Vermont contracted providers to serve in an advisory capacity to the quality management or other designated committee, with additional specialist input as needed. If an advisory committee is selected, the managed care organization shall document that the committee provides written input to the quality management program at least annually, and that such input is considered for incorporation into the quality management program.
 5. A systematic approach to seeking input from the managed care organization's members and incorporating that input into the managed care organization's quality management program. The managed care organization may address this requirement by establishing a committee of at least three (3) Vermont members to serve in an advisory capacity to the quality management or other designated committee, or by annually convening focus groups of Vermont members to provide input on quality management topics. The managed care organization shall document that consumer input is at least annually received by and incorporated into the quality management program.

6. Policies and procedures that ensure that the managed care organization's contracted providers and members expressing interest in participating in the development, implementation, and evaluation of the quality management program have the opportunity to do so.
 7. An opportunity for members and contracted providers to comment on the quality management process.
- (F) The managed care organization shall consult with contracted providers to develop and implement a satisfactory process to minimize the administrative burdens on providers (especially for those providers in small group practices) of implementing the quality improvement activities in Sections 6.3(B)7 and 6.3(B)8.

6.3 Quality Management Program Description and Activities.

- (A) Quality Management Program: Each managed care organization shall have an internal quality management program that monitors and evaluates processes and outcomes of care for the full range of its health care services across all institutional and non-institutional settings and works with contracted providers to improve the quality of those services; and that monitors, evaluates and improves the managed care organization's service to its members and providers. A summary of the program shall be made available to managed care organization staff, contracted providers and members of a managed care organization upon request. The use of quality management program data to design incentives for members to use specific contracted providers shall not be implemented without Department approval and shall not reduce the member benefits otherwise applicable.
- (B) Written Quality Management Program Description: The quality management program described in Subsection 6.3(A) shall include an annual written quality management program description that describes how the managed care organization intends to:
1. analyze data pertaining to diagnoses; procedures; service over-use, under-use and misuse; member and provider satisfaction; member grievances; and member demographics to identify managed care organization practices and health care diagnoses, procedures and services that affect a substantial number of the managed care organization's members, that could place members at serious risk, that could create significant dissatisfaction among members or contracted providers, or that indicate potential opportunities for improvement. This section shall not be construed to require a managed care organization to review every disease, illness and condition that may affect a member;
 2. analyze both processes and outcomes of care using defined measurement methodologies to discern the causes of variation;
 3. compare program findings with past performance, as appropriate, and with pre-established internal goals and external standards adopted by the managed care

organization (such as industry-recognized regional and national benchmarks), where available;

4. implement improvement strategies related to program findings;
5. prospectively assess the potential adverse impacts of improvement strategies on members with mental health or substance abuse conditions, and take steps to minimize such impacts;
6. ensure that all quality improvement strategies are informed by generally accepted medical or scientific evidence, if available, and do not pose a foreseeable risk of harm to members;
7. in order to improve care across the contracted provider network, use program findings to work, on a continuing basis, with contracted providers and other staff to improve the health care delivered to its members. The managed care organization shall work directly with contracted providers to continually improve performance over time, through constructive engagement, provision of motivation and support, and processes to promote accountability. Such efforts shall at a minimum include high volume contracted providers located throughout the state, and shall annually include the following:
 - a. Delivering managed care organization statewide and provider-specific performance data, including data on chronic care measures, that compare the provider to a standard, goal, or managed care organization norm, including multiple dimensions of quality where meaningful opportunities for improvement exist for two (2) or more of the following: provider accessibility, clinical quality, efficiency of clinical practice and/or patient experience of care. Performance shall be measured for primary care physicians; specialist physicians; mental health and substance abuse providers; acute care hospitals; hospitals providing inpatient mental health and substance abuse services; and any other provider type specified by the Department;
 - b. Providing performance data at the individual provider level if statistically meaningful. If the data are not statistically meaningful at the individual provider level, the managed care organization shall conduct measurement at the next level (practice site or group practice) at which it is statistically meaningful;
 - c. Reviewing and discussing performance results directly, by telephone or in person, with high-volume providers or the provider's designee;
 - d. Identifying opportunities for improvement and provider improvement goals based on provider performance data;

- e. Assessing performance relative to provider improvement goals; and
 - f. Motivating and supporting high-volume provider efforts to generate quality improvement through the use of provider incentives and the provision of resources to assist providers in improving performance.
8. In order to assist providers who do not meet managed care organization quality standards, at least annually measure the performance of high volume contracted providers and:
- a. Adopt and publish quality standards for primary care physicians, specialists (including mental health care providers) and hospitals;
 - b. Measure and report results to providers;
 - c. Identify providers, provider sites and/or provider practices that do not meet the managed care organization's standards;
 - d. Take appropriate action to correct deficiencies, including establishing corrective action plans with providers;
 - e. Monitor providers to determine where they have implemented corrective action; and
 - f. Take appropriate and significant action when a provider has not implemented corrective action, including but not limited to requesting the credentialing verification committee to initiate a review of the provider's performance.
9. Maximize the number of members receiving care consistent with treatment protocols and practices that are informed by generally accepted medical and scientific evidence and practice parameters consistent with prevailing standards of medical practice as recognized by health care professions in the same specialties as typically provide the procedure or treatment, or diagnose or manage the medical condition, and that are developed with the appropriate clinical input. The managed care organization shall review the protocols and practices at least once every two (2) calendar years, or more often if practice standards change; and employ substantive incentives for contracted providers to improve their adherence to accepted protocols and practices.
10. If indicated, improve access to care for members according to travel and waiting time standards established in this rule by developing policies to support travel and waiting time standards, disseminating waiting time standards to providers, at least annually assessing waiting times for services, reporting findings to contracted providers, and taking action to improve access where indicated by the assessment of waiting times for services;

11. Promote the use of preventive health services by:
 - a. Adopting practice guidelines specific to preventive health services that are based on reasonable medical evidence; and
 - b. Establishing effective procedures for informing members on at least an annual basis about preventive health services available to them;
 12. Inform members in hard copy, on the internet, or in an electronic mailing, at least annually, about health promotion programs available to them, such as smoking cessation courses, nutritional courses, and weight loss programs; and
 13. Conduct an annual quality management program evaluation that includes an evaluation of the effectiveness of the strategies implemented in paragraph 4 of this subsection.
- (C) Each managed care organization shall develop an annual quality management work plan containing a written description of clinical and administrative quality improvement activities, including improvement goals and attendant measures, project timelines, accountable persons, data collection activities and how the activities meet objectives of the quality management program. The quality management work plan will also clearly identify quality improvement goals agreed upon with the Department (or, at the discretion of the Department, selected by the managed care organization) and reported to the Department under Section 6.4(B).
- (D) The quality improvement activities in Sections 6.3(B)7 and 6.3(B)8 may be implemented by a managed care organization on an individual basis or undertaken as a joint quality improvement project together with one (1) or more other managed care organizations subject to this Part and shall meet the following requirements:
1. By January 1, 2010, each managed care organization shall have established participation in at least two (2) joint quality improvement projects with one (1) or more other managed care organizations. This requirement differs from and is in addition to joint quality improvement projects between a health insurer and a managed care organization or mental health review agent that manages the mental health benefits for the health insurer's health benefit plan, including the project required in Subsection 6.4(C).
 2. Each managed care organization shall include the joint projects in its annual quality improvement work plan filed with the Department in 2010; shall implement the projects during calendar year 2010; and shall thereafter include at least two (2) joint projects in its annual quality improvement work plan and continue to participate in at least two (2) joint quality improvement projects on an ongoing basis, subject to Subsection 3 of this section. The Commissioner, in her or his sole discretion, may determine whether a joint quality improvement project meets the requirements of this section.

3. By December 31, 2012, the Department will make a determination as to the scope and level of accomplishment of joint quality improvement efforts by managed care organizations. Based on that determination, the Commissioner, in her or his sole discretion, may require managed care organizations to participate in additional joint quality improvement projects. Thereafter, based on further review of joint quality improvement projects undertaken by all of the managed care organizations then subject to this Part, the Commissioner may determine that joint quality improvement projects have achieved a scope and level of accomplishment that would eliminate the need for separate, individual managed care organization quality improvement projects to meet certain requirements specified in Sections 6.3(B)7 and 6.3(B)8 of this rule.
 4. In addition, managed care organizations shall actively participate in quality improvement initiatives aimed at improving public health that are sponsored by the Department of Health, Agency of Human Services, Agency of Administration and/or other State agencies. Managed care organizations shall also cooperate with the Department and its quality improvement contractors in conducting clinically-focused studies, developing clinical practice guidelines, participating in joint quality improvement activities, and/or consistently attending Department meetings, when invited.
- (E) Managed care organizations may use quality management activities undertaken to satisfy the requirements of other entities, including independent accreditation programs, to meet the requirements of this section to the extent those activities otherwise meet these requirements.
- (F) At least once every three (3) years after the initial verification of credentials, during recredentialing of contracted providers, each managed care organization shall conduct a performance appraisal of high volume primary care providers and specialists, to include a review of member complaints, clinical quality performance, and efficiency data specific to the provider. Alternatively, the managed care organization may conduct such performance appraisal between recredentialing cycles and, if issues are identified, demonstrate that the issues are brought to the attention of the managed care organization's credentialing committee for review and action. The managed care organization shall adjust for provider case mix when evaluating efficiency data. Such a performance appraisal shall include a comparison of the provider's performance against quantitative thresholds established by the managed care organization representing managed care organization standards that have been communicated to contracted providers in advance of the performance appraisal period. If the credentialing committee determines that an action that will negatively affect a provider's contracted status is warranted and the determination is based on the components of the performance appraisal that were derived from claims data, the managed care organization shall confirm those results with a review of medical records prior to taking action if requested by the provider.

(G) Each managed care organization shall engage in quality improvement activities that result in improvements in the quality of care and service provided to the managed care organization's Vermont members as compared to the managed care organization's performance from immediately preceding years. Quality of care shall be evaluated by using measures that have been developed, adopted or deemed appropriate for quality measurement by national organizations with recognized expertise in quality measurement, such as the National Committee for Quality Assurance, the National Quality Forum, the Centers for Medicare and Medicaid Services and the Ambulatory Quality Alliance, and that are annually filed with the Department pursuant to Section 6.6. The Department in its sole discretion may waive certain requirements in Section 6.3 if the managed care organization demonstrates compliance with this subsection. Areas to be evaluated by the Department for improvement include:

1. Member service, satisfaction and experience of care;
2. Preventive care;
3. Acute illness care; and
4. Chronic illness care.

6.4 Annual Quality Improvement Goals.

(A) The managed care organization shall annually identify quality improvement goals and associated projects being pursued for Vermont members contained in the annual quality management work plan required by Section 6.3(C) of this rule, and shall define quantitative metrics to assess goal attainment in accordance with guidance established by the Department. The goals and associated projects shall be negotiated with the Department. The Department may, in its sole discretion, allow a managed care organization to select its own quality improvement goals and associated projects through an alternative quality improvement goal process if the Department determines that the managed care organization has demonstrated the ability to select goals and associated projects that meet the requirements of this rule. The quality improvement goals shall be based on opportunities for improvement identified through:

1. the Department's evaluation of the annual filing referenced in Section 6.6(B) of this rule;
2. the managed care organization's evaluation of the quality of care provided to its members; and
3. other appropriate sources of data regarding health care quality.

(B) The managed care organization shall provide progress reports to the Department on the quality improvement goals semi-annually, or annually if the managed care organization is determined to be eligible for the alternative quality improvement goal process described

in Subsection 6.4(A) of this rule. The Department shall evaluate the managed care organization's quality improvement goals using one (1) or more of the following criteria:

1. Whether the goals are of adequate breadth in terms of the number and degree of difficulty of the goal activities and interventions;
 2. Whether the managed care organization made a good faith effort to achieve each goal; and
 3. Whether improvement has been achieved.
- (C) When a health insurer contracts with another managed care organization or a mental health review agent to manage the mental health benefits for a health benefit plan subject to this Part, a minimum of one (1) of the quality improvement projects to be completed annually shall be a joint project between the health insurer and the managed care organization or mental health review agent that manages the mental health benefits. The project shall be reported to the Department under Section 6.4(B). The project shall implement policies and incentives to increase collaboration among providers, with the goal of facilitating clinical integration of services for medical and mental health conditions. The project shall:
1. include evidence of how data collected from the project are being used to inform the practices, policies, and future direction of care management programs for mental health conditions; and
 2. demonstrate how the project is supporting the incorporation of best practices and evidence-based guidelines into the utilization review of mental health conditions.

6.5 Chronic Care Program Requirements.

- (A) Each managed care organization shall develop and maintain a program under the direction of its medical director that is designed to assist its members and their providers in managing chronic conditions in a way that will improve the health status of members who have chronic conditions. If a managed care organization participates in the blueprint for health chronic care initiative, it is deemed to meet the requirements of this section for those geographic areas in which the blueprint for health is active. The Department, in its sole discretion, may determine that the managed care organization is deemed to meet the requirements of this section for the entire state if the managed care organization is participating in the blueprint for health in communities covering a majority of the state's population.
- (B) The managed care organization's program may use the managed care organization's own personnel, or program resources may be provided through a contracted organization. The managed care organization may also elect to support physician practices and/or community care teams that are participating in the blueprint for health in implementing the chronic care program. When such support and implementation occurs, the

Department in its sole discretion may determine that certain requirements in this Section 6.5 are not applicable to the managed care organization.

(C) In developing and maintaining its chronic care program, each managed care organization shall:

1. Identify the prevalence of the chronic conditions that have, or will have, the greatest impact on the health status of the managed care organization's population and focus particular attention on these when developing its chronic care program and services;
2. Recognize that a high percentage of members have more than one chronic condition, and focus on supporting members and health care providers in safely and effectively managing multiple chronic conditions;
3. Ensure that chronic care program activities are coordinated between and among the patient's treating health care providers and case managers, including those providers and case managers addressing mental health and substance abuse issues, unless prohibited by law; and
4. Design the program to accommodate the potential impact of program activities on members with mental health conditions including substance abuse conditions or disorders.

(D) The managed care organization shall systematically and at least monthly identify members who have, or who are at risk for developing, chronic conditions, using the following data sources:

1. Claims or encounter data;
2. Pharmacy data, if applicable;
3. Health risk appraisal results;
4. Laboratory results, if applicable;
5. Data collected through the UM or case management process, if applicable; and
6. Member and provider referrals.

(E) The program shall:

1. Have a mechanism to assess the accuracy of case finding prior to initiating contact with the member;
2. Initiate contact with members in writing and:

- a. Convey clear information regarding the financial or other benefits/consequences of the choice to participate or decline;
 - b. Disclose the qualifications of program staff;
 - c. Explain how the patient's provider will be involved; and
 - d. Elicit the member's preferences regarding telephone contacts and messages.
3. Support condition monitoring by the member and the health care provider;
 4. Maximize member participation in and engagement with the chronic care program and with self-management;
 5. Consider and modify the managed care organization's chronic care support services as needed in response to a member's multiple health conditions; and
 6. Address member lifestyle issues, as indicated by practice guidelines, and also address environmental issues (e.g. – characteristics of home and work settings).
- (F) The managed care organization shall provide members with written chronic care program information regarding:
1. How members become eligible to participate;
 2. How members use the services; and
 3. How members may participate in the chronic care program, and opt in or opt out of the chronic care support services offered by the managed care organization.
- (G) The managed care organization shall provide the most appropriate interventions after stratifying members based on the severity of risk that each member faces and/or the member's assessed readiness to change his or her behaviors.
- (H) The managed care organization shall provide:
1. All members with information regarding community-based self-management support and self-management education resources available to members.
 2. All members participating in chronic care programs with:
 - a. opportunities for office or telephone visits, group meetings and/or written communication for the purpose of action planning, problem solving and other active involvement in the development and ongoing enhancement of their

self-management plans. At the discretion of and with the consent of the member, these activities may be implemented by and with any or all of the following:

- i. qualified members of the primary care provider's practice, including the primary care provider, the practice's care manager, and the practice's care coordinator;
 - ii. a Blueprint Community Care Team care manager, if available;
 - iii. a managed care organization care manager or care coordinator;
 - b. ongoing self-management education and self-management support to develop and enhance the member's self-management skills; and
 - c. processes and tools to track adherence to the member's self-management plan.
- (I) The managed care organization shall integrate information from the following systems to facilitate access to member health information for continuity of care:
 1. A health information line or web-based health information resource;
 2. A disease management program;
 3. A case management program; and
 4. A utilization management program, if applicable.
- (J) The managed care organization shall provide written chronic care program information to providers regarding:
 1. Instructions on how to access, use, and coordinate with the managed care organization's chronic care program and services; and
 2. How the chronic care program and services work with the health care provider's patients in the program.
- (K) The managed care organization shall assist, support and provide incentives to all contracted primary care practices to better manage chronic conditions by:
 1. Offering access to provider and practice-specific patient-level data and reports that will aid them in their efforts to provide good chronic care, such as patients admitted to or discharged from inpatient care, patients who have and have not received recommended outpatient care;

2. Providing information regarding community-based self-management support and education resources available to members and providers;
3. Offering tools to track adherence by the member to the member's self-management plan;
4. Motivating and supporting primary care providers in:
 - a. Using office-based information systems that support chronic care, such as electronic registries;
 - b. Providing team-based care by primary care providers;
 - c. Providing services that support chronic care management, but have not historically been covered;
 - d. Conforming with evidence-based guidelines for chronic care;
 - e. Integrating a care coordination/care management function within the primary care practice; and
 - f. Obtaining recognition through formal programs that encourage the use of team-based, systematic, patient-centered, coordinated care management processes such as the Physician Practice Connections[®] – Patient-Centered Medical Home[™] program of the National Committee for Quality Assurance.

(L) The managed care organization shall use the following mechanisms to assess the effectiveness of the chronic care program:

1. Annual measurement of member participation rates;
2. Annual measurement of the effectiveness of the chronic care program. Each measurement shall:
 - a. address a relevant process and outcome;
 - b. produce a quantitative result;
 - c. be population-based;
 - d. use data and methodology that are valid for the process or outcome being measured; and
 - e. be analyzed in comparison to an established benchmark or goal;

3. Annual evaluation of perceptions of and satisfaction with its chronic care program among members who participate as well those who opt out of the chronic care support services offered by the managed care organization; and
4. Annual evaluation of contracted health care providers' perceptions of and satisfaction with its chronic care program.

6.6 Baseline, Annual and Periodic Review Filing Requirements.

- (A) Baseline Review Filing: Each managed care organization shall file baseline review documentation to be specified by the Department related to its policies, procedures, member communications and provider contracts.
- (B) Annual Filing: Each managed care organization shall file a copy of its quality improvement work plan prepared pursuant to the requirements of this rule on an annual basis on or before March 31 or another date as determined by the Commissioner. Each managed care organization shall file the following performance and other information in accordance with the Department's specifications on an annual basis, on or before July 15 or another date as determined by the Commissioner. The Department may impose these annual filing requirements on a more frequent basis as it determines is warranted:
 1. Service access indicators; for example, geographic proximity and wait time to obtain services;
 2. Specific utilization indicators; for example, primary care physician and emergency room visits per one thousand (1,000) members;
 3. Preventive care indicators; for example, the percentage of children and adults who receive recommended preventive services, by type of service;
 4. Coordination and continuity of care indicators;
 5. Acute and chronic care indicators; for example, the percentage of diabetics who receive recommended services, by type of service;
 6. Indicators that assess provider adoption of and managed care organization support for Blueprint for Health concepts and practices; for example, the percentage of contracted primary care practices that have been recognized for Blueprint adoption and the percentage of practices that are receiving enhanced reimbursement to support Blueprint implementation and operation;
 7. Indicators of member grievances, including but not limited to their frequency, type, and the timeliness and nature of their disposition, and the managed care organization's register or log of member grievances;

8. Indicators of utilization management activities, including but not limited to their frequency, type, and the timeliness and nature of their disposition;
 9. Member enrollment and disenrollment figures;
 10. The numbers and percentages of provider-initiated terminations and plan-initiated terminations of providers in the prior year;
 11. The results of annual member and provider satisfaction surveys using, at a minimum, a standardized state-approved member satisfaction survey instrument and a standardized state-approved provider satisfaction survey instrument;
 12. Demographic characteristics of its membership;
 13. Efficiency indicators; for example, relative resource use indicators or resources used to treat a commonly defined condition or to perform a commonly defined procedure and related services;
 14. Provider directories;
 15. Any other health status, outcome or performance measures specified by the Department; and
 16. Material changes to policies, procedures, member communications, provider contracts or any other documents required by this rule.
- (C) Each managed care organization shall cooperate with the Department to ensure that data reporting requirements are standardized, to the extent possible, so that comparable data can be collected on a statewide basis.
- (D) Periodic Review Filing: Each managed care organization shall file periodic review documentation to be specified by the Department, related to its policies, procedures, member communications, provider contracts and operational practices. Periodic review requirements shall emphasize:
1. Documentation to be specified by the Department related to requirements with which the managed care organization has demonstrated non-compliance in prior Baseline and Periodic Review activities; and
 2. Demonstration that, in addition to policies and procedures, the managed care organization's operational practices are compliant with requirements of this rule.

6.7 Baseline and Periodic Review Procedures.

- (A) Baseline Review:. Upon application of a managed care organization for authorization to conduct business in Vermont or at any other time as determined by the Department, the

Department shall conduct a review to ascertain the managed care organization's ability to comply with the requirements of this rule and to ensure acceptable standards of quality for its members. This review will be carried out through assessment of the documentation submitted by the managed care organization as required by this rule and by review of any other records or other examination as deemed necessary by the Department.

- (B) Periodic Review.: The Department shall conduct periodic reviews of managed care organizations at least once every three (3) years, and more frequently as the Department in its discretion deems proper to ascertain the managed care organization's compliance with the requirements of this rule. This review will be carried out through the assessment of documentation submitted by the managed care organization as required by this rule and by review of any other records or other examination as deemed necessary by the Department, and may include an on-site review of the managed care organization and/or its delegate(s).

6.8 Independent Accreditation Organizations.

- (A) A managed care organization may be deemed to have fulfilled the requirements of this rule that are determined by the Commissioner to be able to be met through accreditation by an independent accreditation organization approved by the Department. The independent accreditation organization shall be capable of analyzing, in an in-depth manner, a managed care organization's provision of quality health and health care to its members.
- (B) The Department shall promulgate a list of approved independent accreditation organizations that it has determined meet the following criteria:
1. The independent accreditation organization has demonstrated to the satisfaction of the Department that it is capable of reviewing and analyzing a managed care organization's quality management program as required by Sections 6.2 and 6.3 of this rule;
 2. The independent accreditation organization has experience in assessing quality of care and quality improvement for managed care organizations;
 3. The standards used by the independent accreditation organization are made available to the Department; and
 4. The independent accreditation organization is capable of preparing and submitting to the managed care organization a written report summarizing the scope of its review, its findings, and its recommendations for improvement, if any.
- (C) The managed care organization shall cooperate with the independent accreditation organization to resolve any problems with its quality management program identified by the organization in its report.

- (D) A copy of the independent accreditation organization's written report shall be made available to the Department during baseline and periodic review(s), within thirty (30) days of receipt of any updated report by the managed care organization, and at any other time upon request by the Department, together with a statement by the managed care organization as to how it intends to address any problems identified in the written report and any applicable time lines in so doing.